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(12) **United States Patent**
Fawzi et al.

(10) **Patent No.: US 6,471,709 B1**
(45) **Date of Patent: Oct. 29, 2002**

(54) **EXPANDABLE RING PERCUTANEOUS TISSUE REMOVAL DEVICE**

(75) Inventors: **Natalie V. Fawzi**, Belmont; **D. Laksen Sirimanne**, Palo Alto; **George D. Hermann**, Portola Valley; **Douglas S. Sutton**, Pacifica; **Thomas A. Howell**, Palo Alto, all of CA (US)

(73) Assignee: **Vivant Medical, Inc.**, Mountain View, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/449,006**

(22) Filed: **Nov. 24, 1999**

Related U.S. Application Data

(63) Continuation of application No. 09/184,766, filed on Nov. 2, 1998, now Pat. No. 6,036,698, which is a continuation-in-part of application No. 09/183,590, filed on Oct. 30, 1998, now abandoned.

(51) **Int. Cl.**[7] **A61B 17/24**
(52) **U.S. Cl.** **606/114**; 600/562
(58) **Field of Search** 606/114, 39, 45, 606/167; 600/562, 564, 566, 567

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Assistant Examiner—Michael B. Priddy
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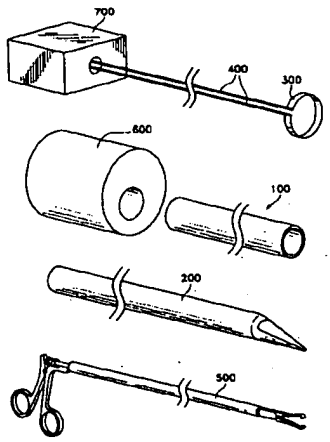
(57) **ABSTRACT**

This is a device for percutaneous tissue sampling or excision. In particular, it uses an expandable ring cutter which produces an accurately located, discrete tissue mass that is removable through a comparatively much smaller access member. The tissue mass is easily reconstructed to its original form and orientation once taken from the body for further study.

57 Claims, 14 Drawing Sheets



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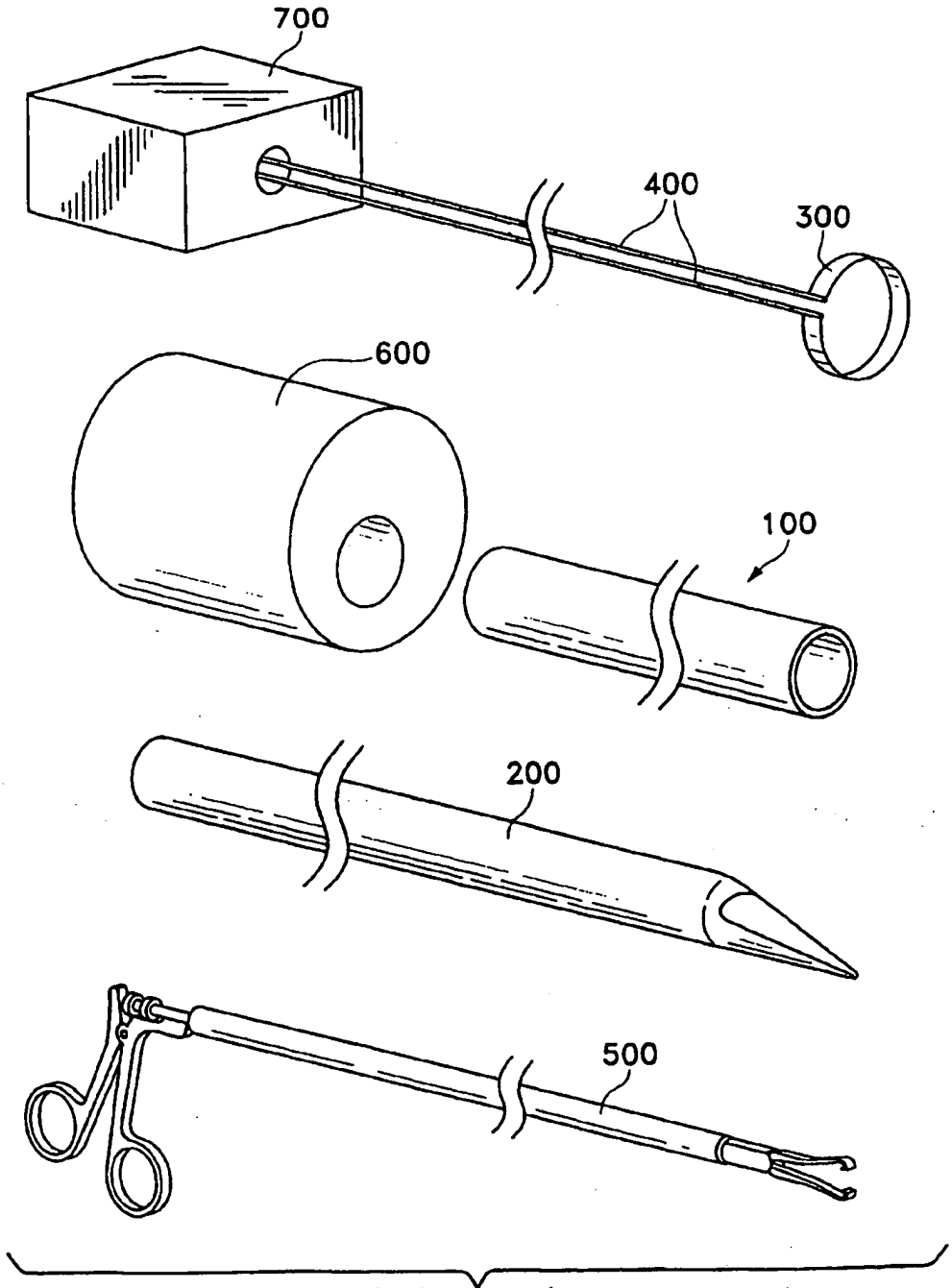


Fig. 1

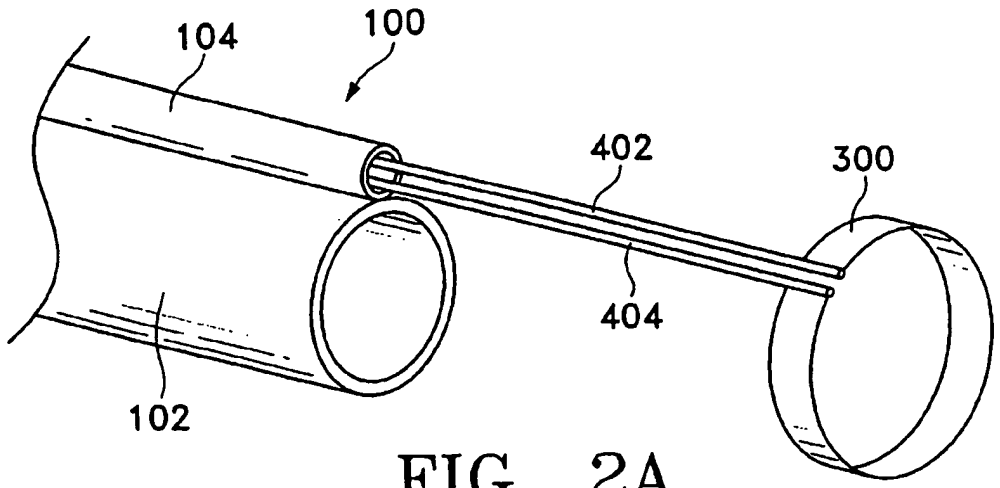


FIG. 2A

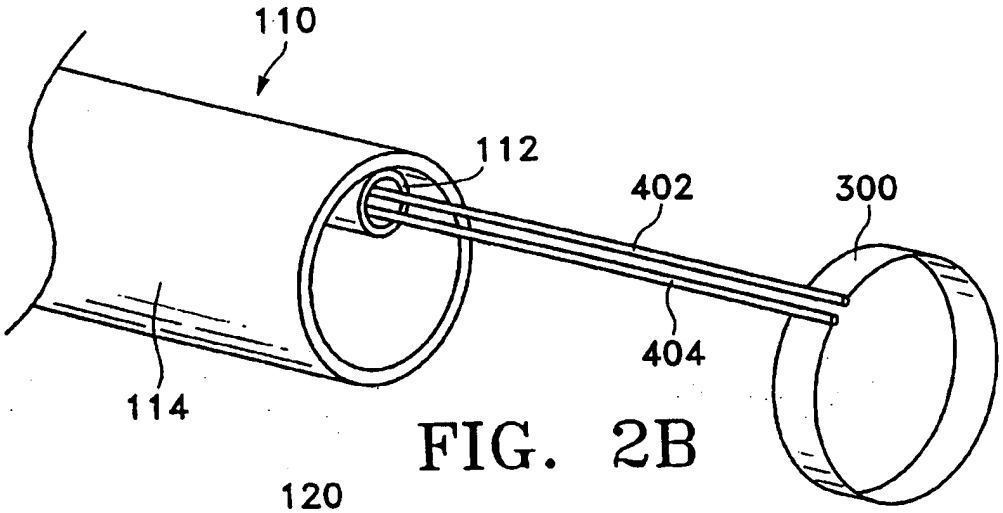


FIG. 2B

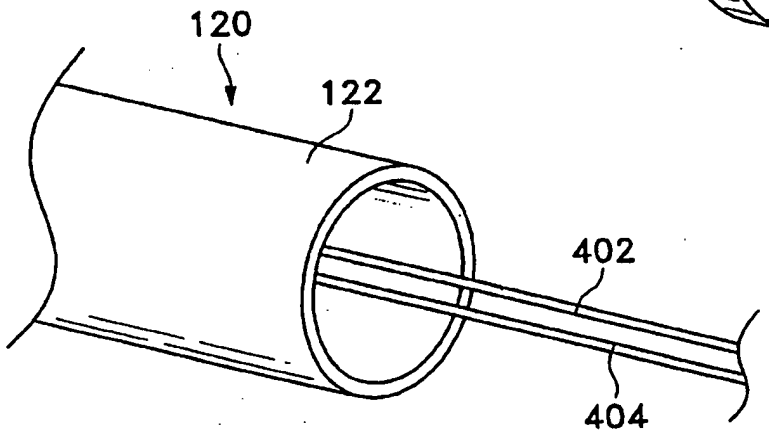
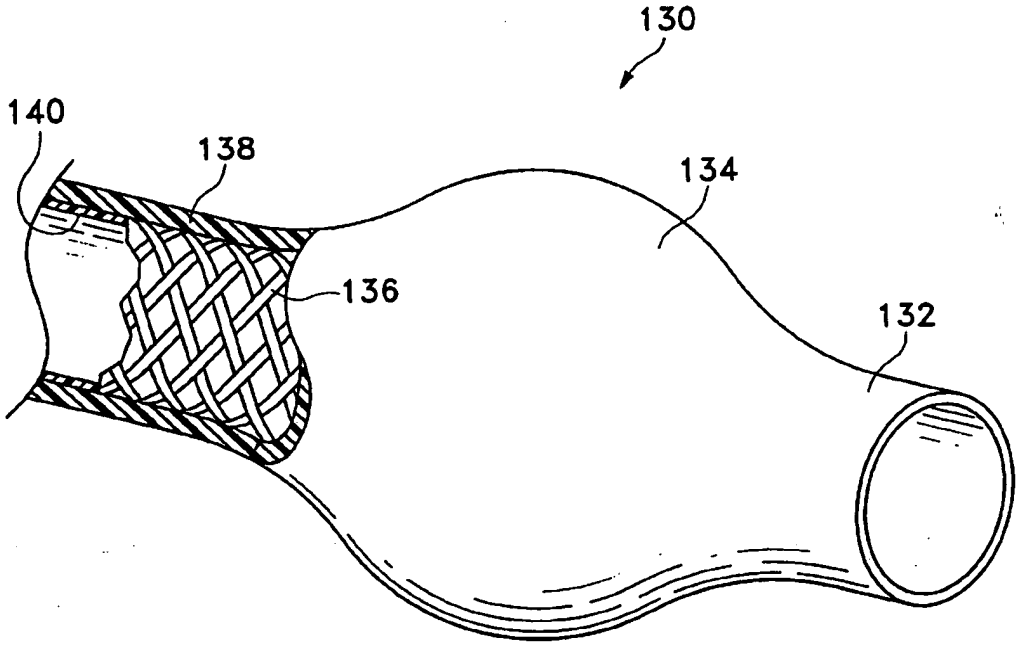


FIG. 2C



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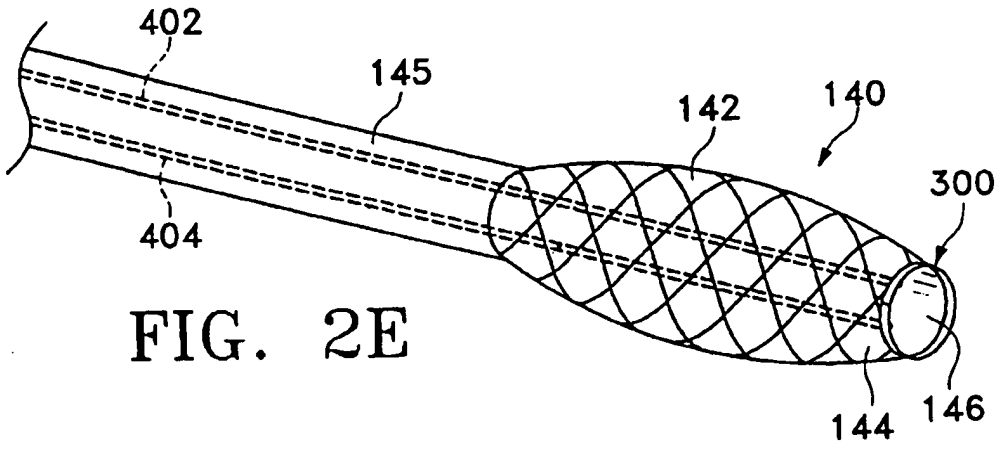
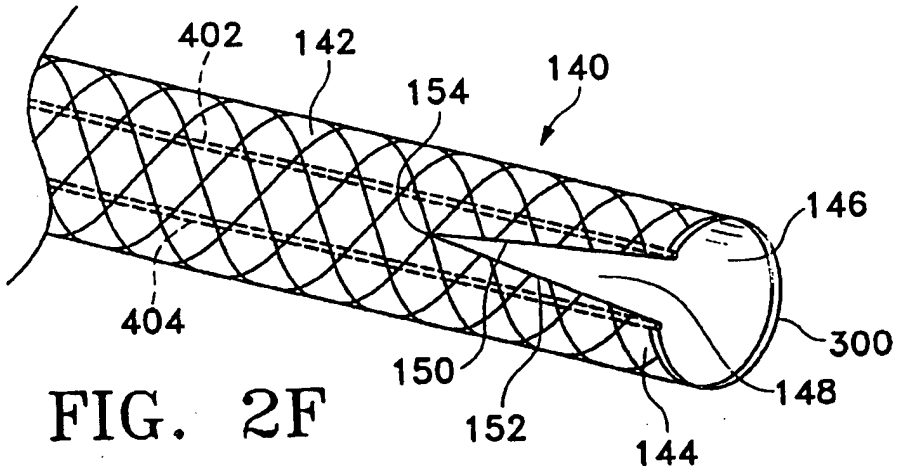


FIG. 2E



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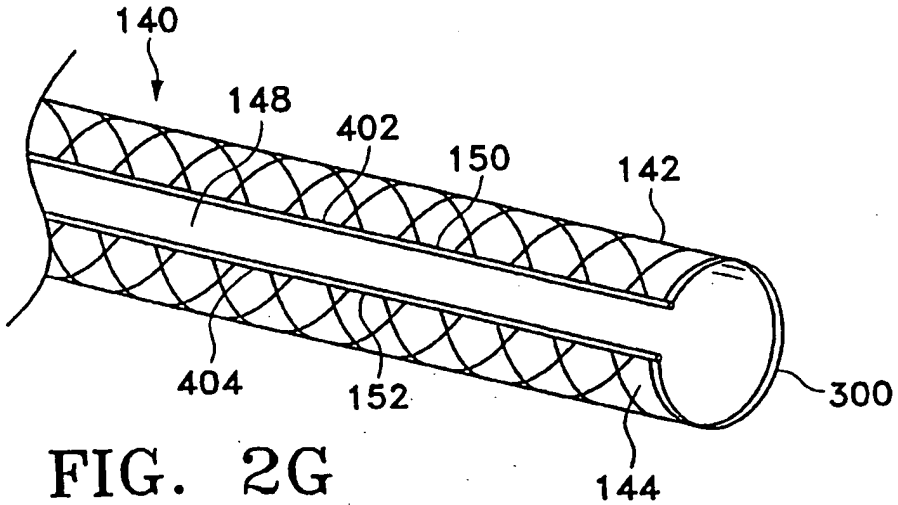

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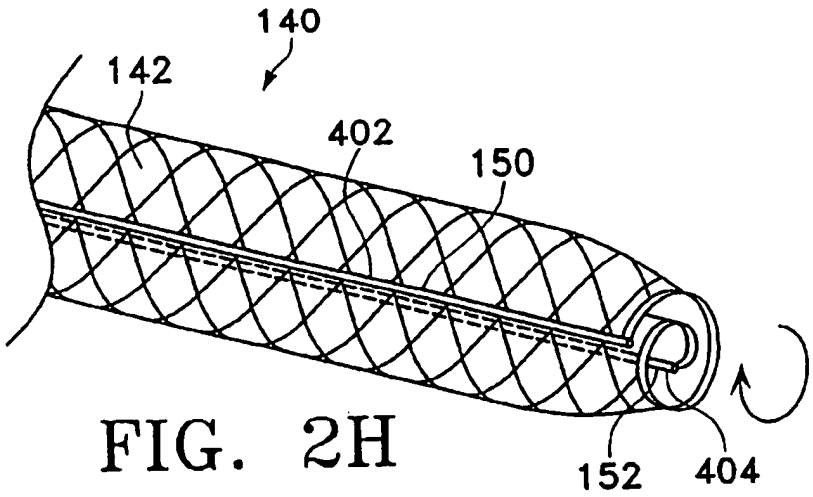

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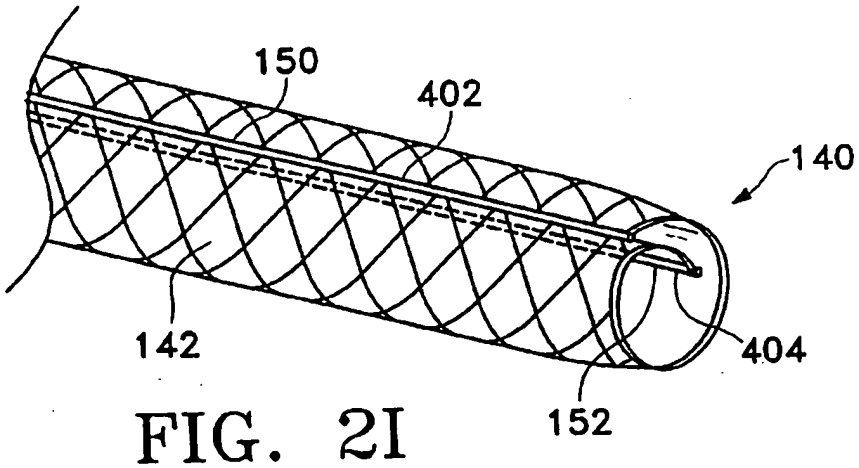

FIG. 2I

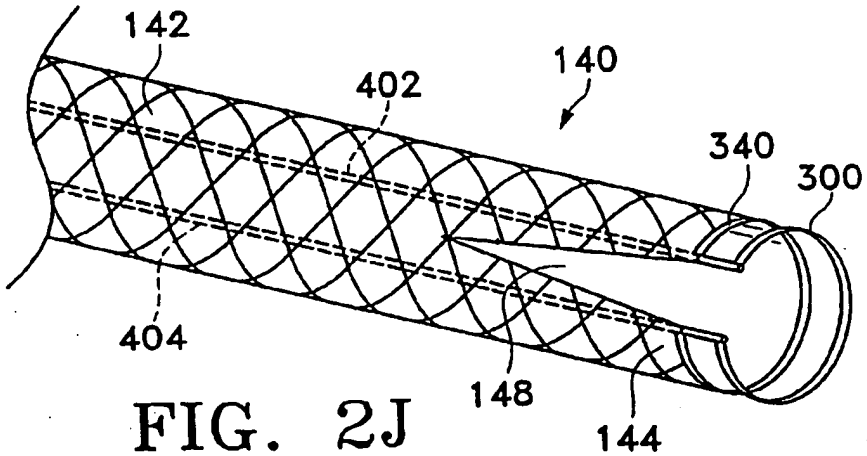

FIG. 2J

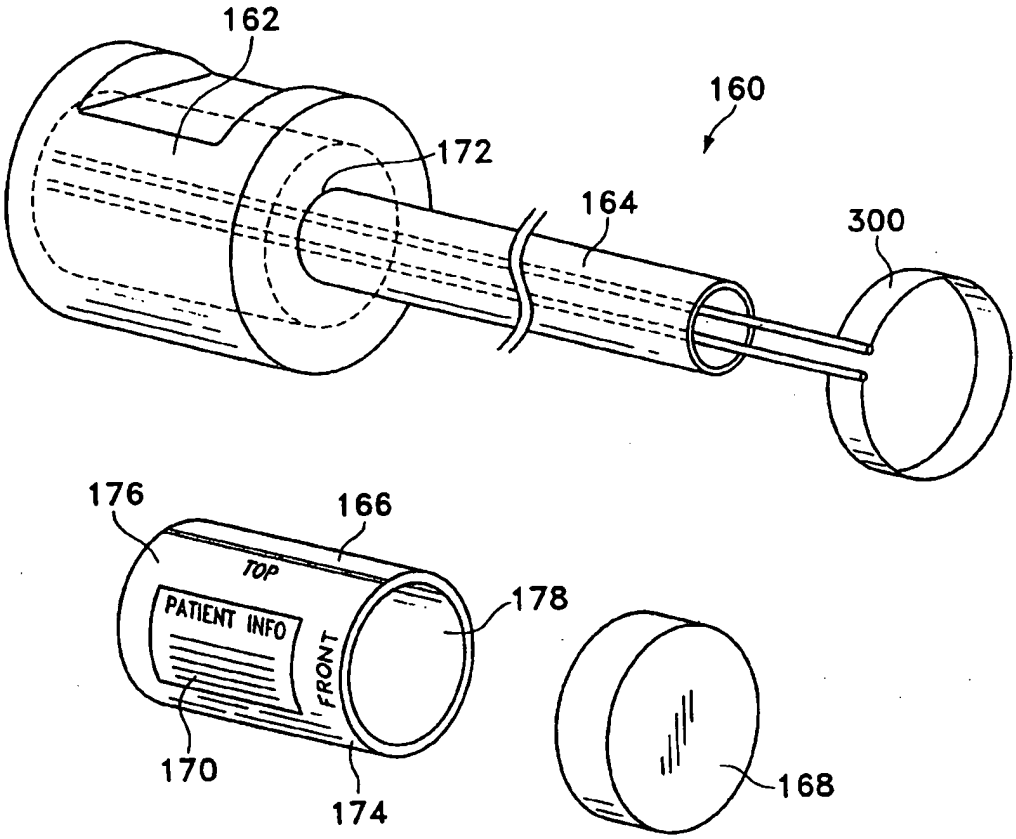
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FIG. 3

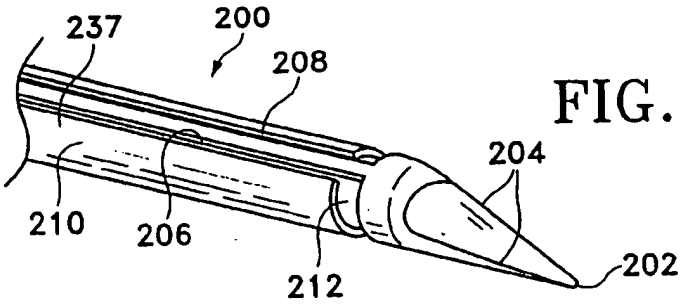


FIG. 4A

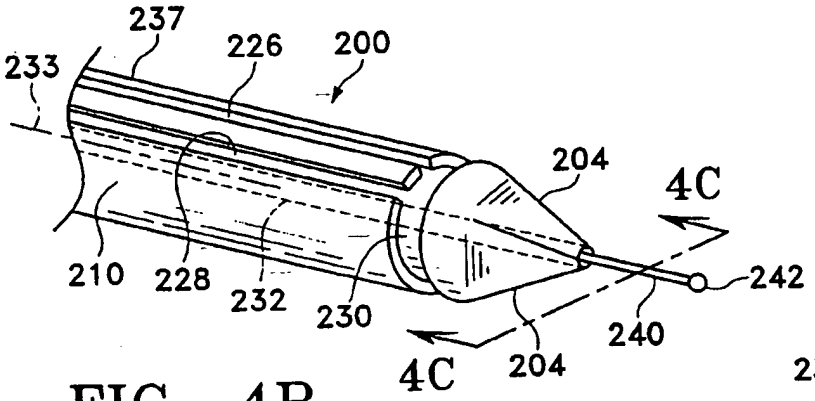


FIG. 4B

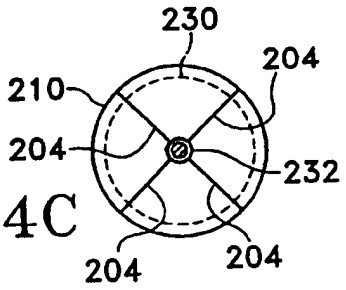


FIG. 4C

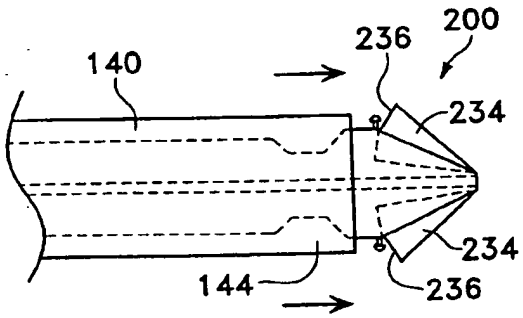
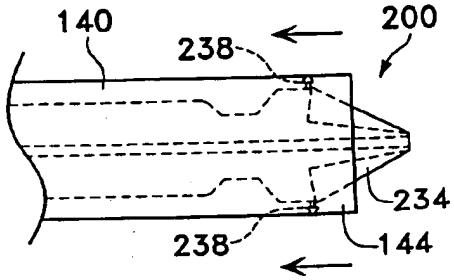


FIG. 4D



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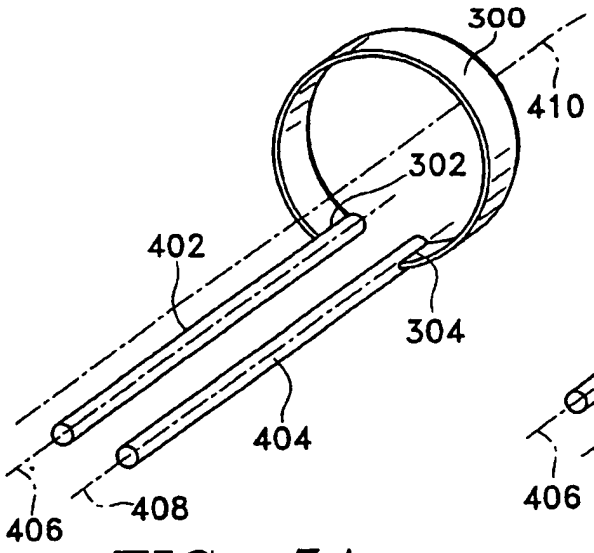


FIG. 5A

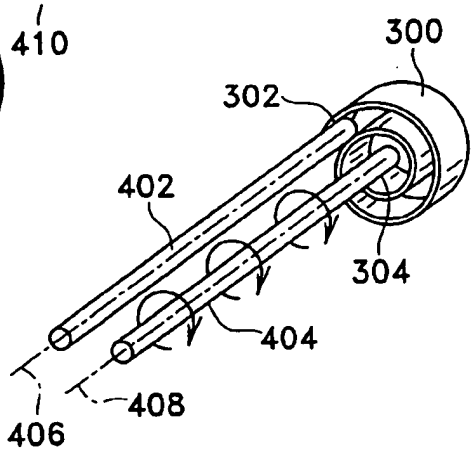


FIG. 6A

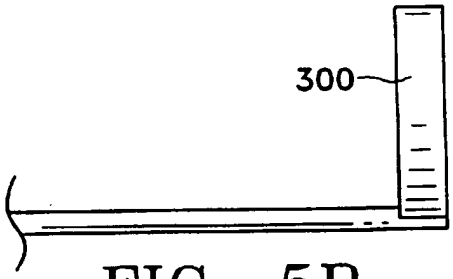


FIG. 5B

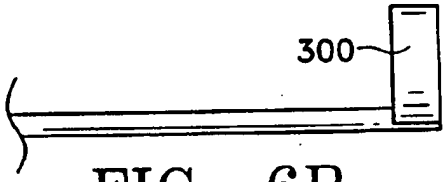


FIG. 6B

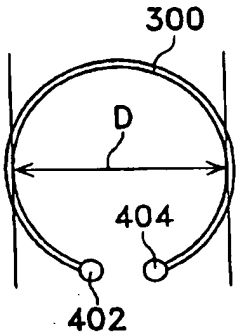


FIG. 5C

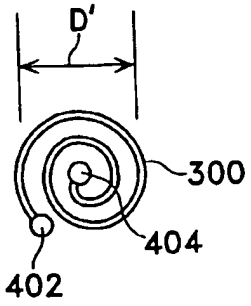


FIG. 6C

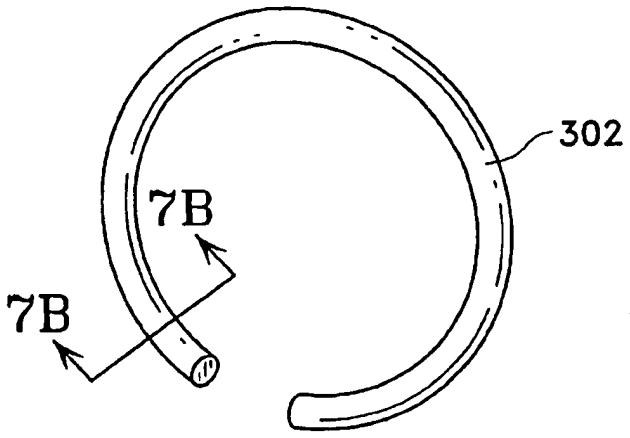


FIG. 7A

FIG. 7B

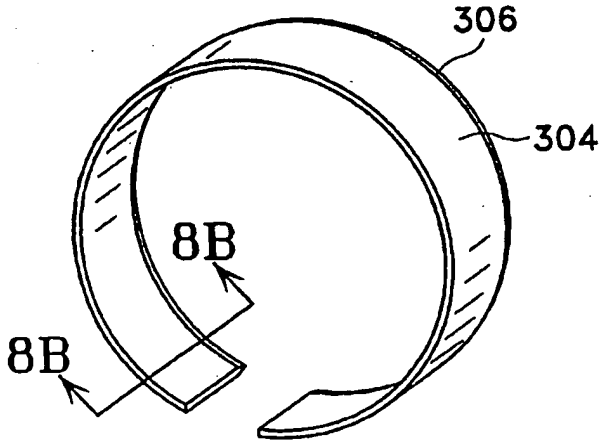


FIG. 8A

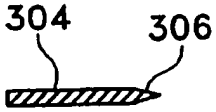


FIG. 8B

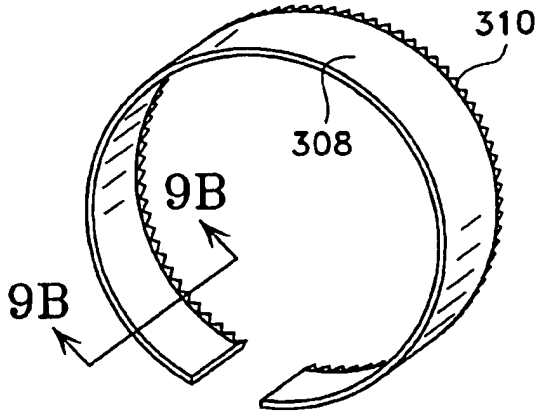
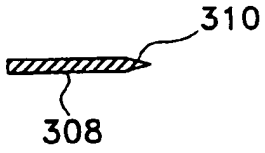


FIG. 9A



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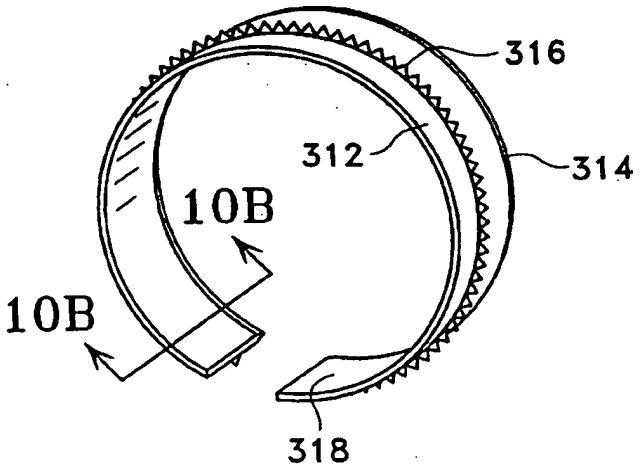

FIG. 10A

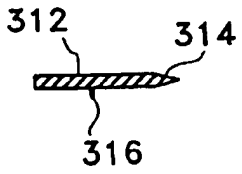

FIG. 10B

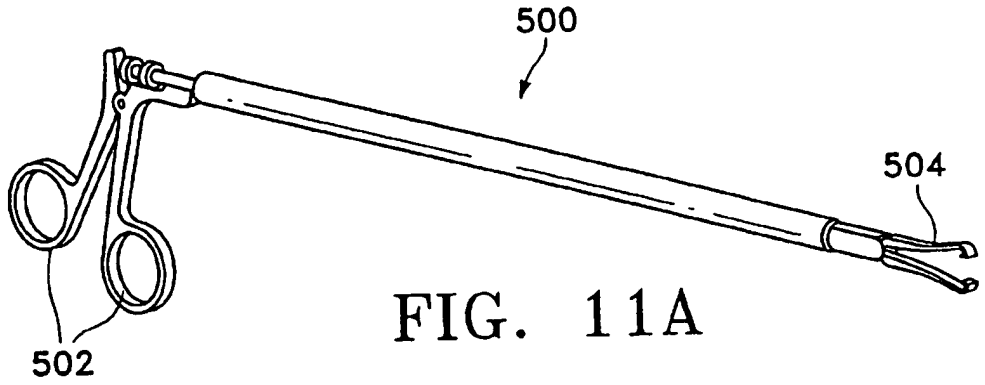

FIG. 11A

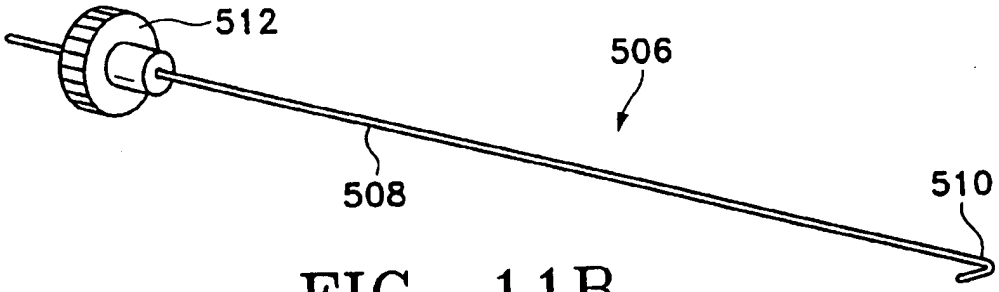

FIG. 11B

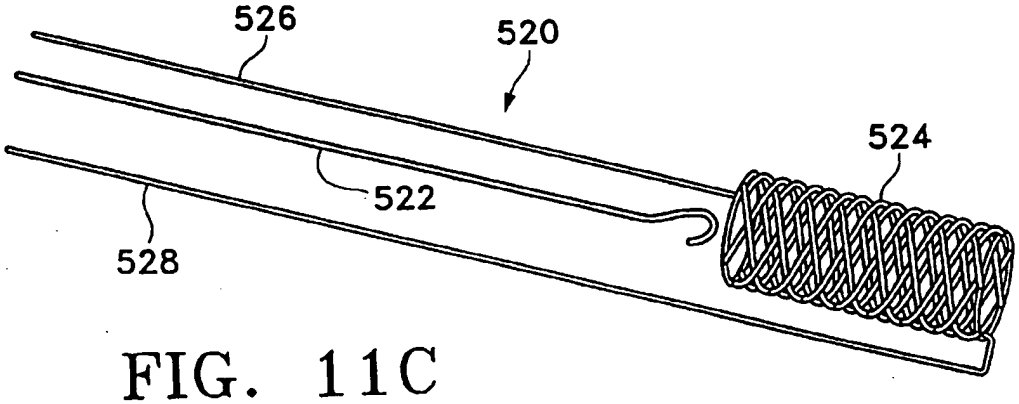

FIG. 11C

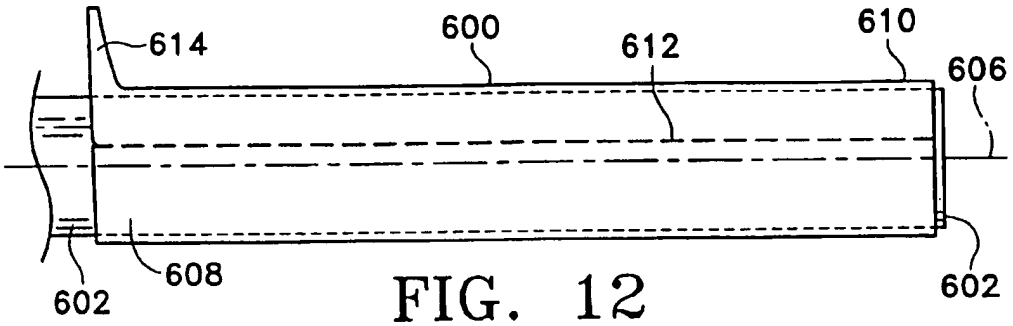

FIG. 12

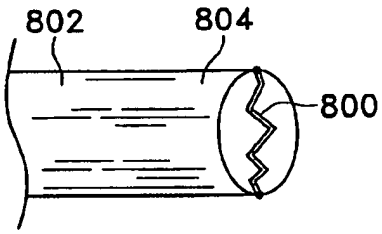

FIG. 13A

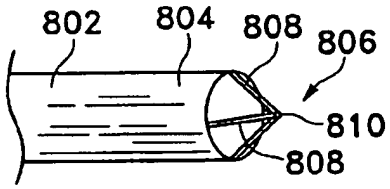

FIG. 13C

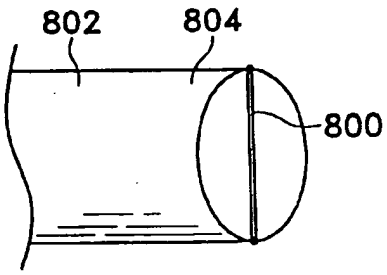

FIG. 13B

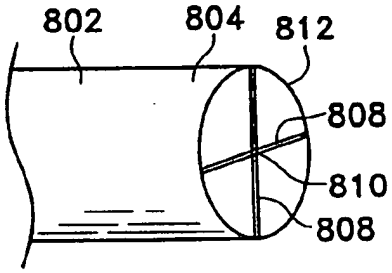

FIG. 13D

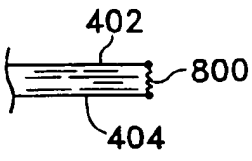

FIG. 13E

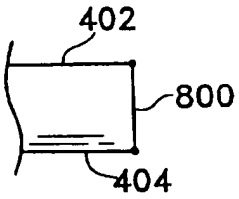

FIG. 13F

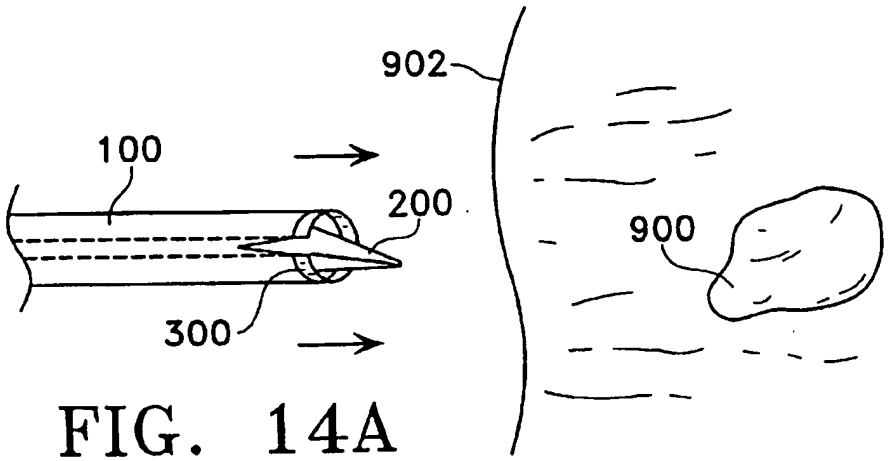

FIG. 14A

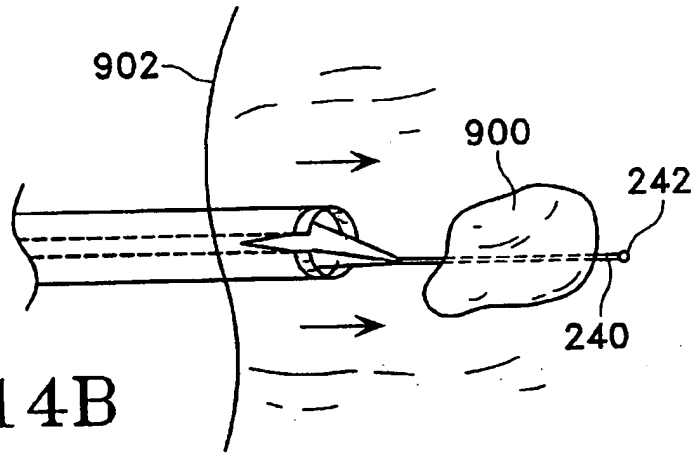

FIG. 14B

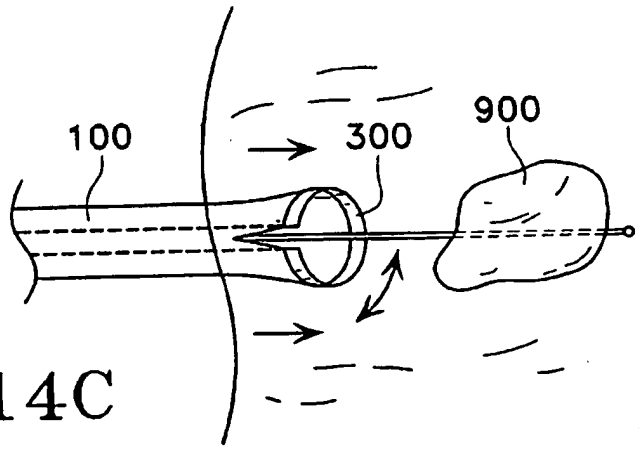

FIG. 14C

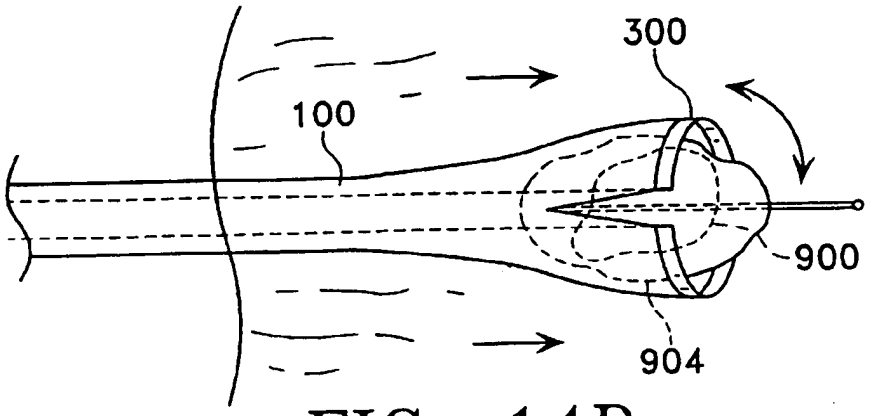

FIG. 14D

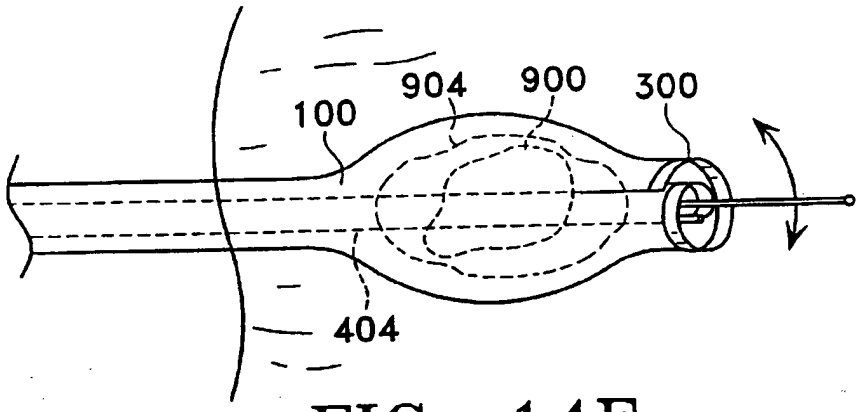

FIG. 14E

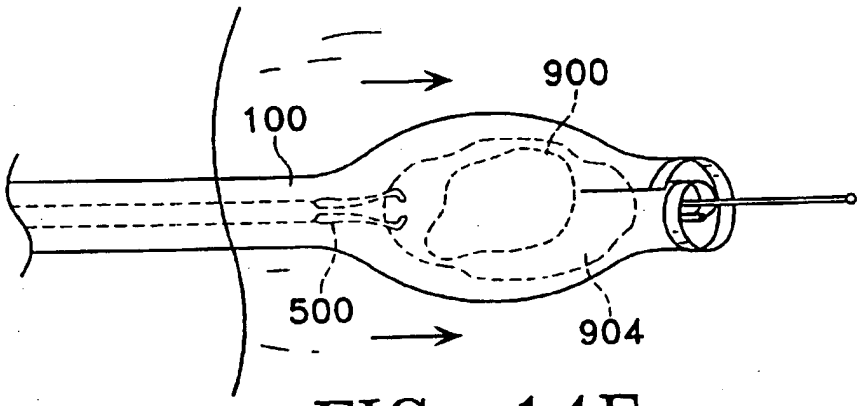

FIG. 14F

EXPANDABLE RING PERCUTANEOUS TISSUE REMOVAL DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 09/184,766, filed Nov. 2, 1998, now U.S. Pat. No. 6,036,698 which is a continuation-in-part of U.S. application Ser. No. 09/183,590, filed Oct. 30, 1998, now abandoned the entirety of which are hereby incorporated by reference.

FIELD OF THE INVENTION

This invention relates to a device and to a related procedure for percutaneous tissue sampling or excision. In particular, it uses an expandable ring cutter which produces an accurately located, discrete tissue mass that is removable through a comparatively much smaller tissue access device. The tissue mass maintains orientation once taken from the body for further study.

BACKGROUND OF THE INVENTION

Despite the advances made in technologies such as medical imaging to assist the physician in early stage diagnosis and treatment of patients with possible atypical tissue such as cancer, it is still often necessary to sample difficult-to-reach organ or tissue lesions by biopsy to confirm the presence or absence of abnormalities or disease.

A disease for which biopsy is a critical tool is breast cancer. This affliction is responsible for 18% of all cancer deaths in women and is the leading cause of death among women aged 40 to 55. As with many diseases and other types of cancer, early detection and diagnosis of breast cancer is critical in providing the best chance of survival.

In the majority of cases, detection of the disease is first made when a patient discovers a palpable mass through self-examination and consults her physician. For breast lesions that are more difficult or impossible to detect through palpation, diagnostic techniques such as x-ray mammography and, more recently, digital mammography, and scintamammography are invaluable. Other techniques such as ultrasound, magnetic resonance, the Dilon gamma camera, position emission tomography, MIBI, computed topography, fluoroscopy, thermography, transillumination and diaphanography can also be used to help determine the presence and nature of suspect tissue.

Of these technologies, the primary clinical diagnostic tool for the detection of breast cancer is x-ray mammography. Over 15 million mammograms are performed each year in the United States alone. Mammography uses x-rays to image breast tissue, identifying areas of high density as possible lesions.

Unfortunately, the limitations of technologies such as mammography in accurately detecting precancerous or cancerous lesions in the breast are significant. Among these limitations is the fact that only one out of every five lesions discovered through x-ray mammography proves to be cancerous. Roughly 25% of women have dense breast tissue, which is notoriously difficult to inspect via mammography. Also, mammography is generally less effective for women under 40 years of age. For younger women, therefore, self-examination for palpable lesions or ultrasound examination is important. However, neither of these techniques is able to detect microcalcifications, important possible precursors to cancer.

As long as there is a degree of uncertainty associated with these various diagnostic techniques, biopsies must be performed to sample the suspicious tissue to determine its exact nature and pathology.

In the detection and treatment of breast cancer, there are two general classes of biopsy: the minimally invasive percutaneous fine or core needle biopsy and the more invasive surgical or "open" biopsy.

Open biopsies, both incisional and excisional, are advisable when suspicious lumps should be removed in their entirety or when core needle biopsies don't give complete information about the nature of the lesion.

One such type of open biopsy is the wire localization biopsy. This procedure includes the following steps: first, a radiologist inserts a wire into the breast under x-ray guidance to mark the location of the suspect tissue. The tissue is then removed by a surgeon for examination by a pathologist. Although large tissue samples are removed by this technique, the risk of permanent disfigurement, the attendant morbidity and mortality risks associated with surgery, and long hospital recovery times are but three of the many disadvantages associated with open surgical biopsies.

Of the less invasive class of percutaneous biopsies, the least invasive is known as a fine needle biopsy. For palpable lumps, a physician inserts a needle and syringe directly into the lump to obtain a cell sample which is then examined by a cytologist. For non-palpable lesions identified by x-ray mammography or other diagnostic tool, fine needle biopsies are often performed under stereotactic or ultrasonic guidance. Here, multiple mammograms are taken of the breast and the images are analyzed by a computer to determine the location of the suspect lesion in three dimensions. The physician then penetrates the breast with a needle, targeting the suspect region and removing a small number of cells. There are two significant drawbacks to fine needle biopsy techniques: first, several specimens must be taken to ensure the lesion is well-sampled. Secondly, the limited size of the specimens obtained under fine needle biopsy dictate that a skilled cytologist be involved to analyze the suspect cells out of context of the surrounding healthy tissue.

A second type of percutaneous needle biopsy used to obtain a larger specimen is known as a core biopsy. With this procedure, a larger needle is inserted into the breast via an incision in the skin under stereotactic or ultrasonic guidance. A spring-loaded device is then fired into the breast to obtain a single core sample of tissue, preferably through the center of the lesion. The larger specimen size (up to 20 mm in diameter) obtained by this technique can be more accurately read by a pathologist, who can analyze the suspect cells in the context of the surrounding tissue. Examples of such devices are described in U.S. Pat. No. Re. 34,056 and U.S. Pat. Nos. 4,944,308 and 4,953,558, the entirety of which are hereby incorporated by reference.

Traditionally, as with fine needle biopsies, core biopsies require multiple core samples, typically four to twenty, to ensure an accurately representative sample of the suspect region is profiled. This means that as many as twenty separate needle insertions must be made into the breast through the skin.

More recently developed needle biopsy technologies are directed to solving this problem by allowing multiple samples to be obtained through a single incision, such as that described in U.S. Pat. Nos. 5,709,697 and 5,782,775, the entirety of which are hereby incorporated by reference. One such technology, described in U.S. Pat. Nos. 5,526,822, 5,769,086, and 5,775,333, the entirety of which are hereby

incorporated by reference, utilizes a trocar-tipped probe which is positioned in the breast under stereotactic or ultrasonic guidance to align the suspect lesion with an aperture that extends along a specified length of the probe. The tissue is then aspirated into the aperture where a rotating cutter in the probe is advanced distally to cut and capture tissue specimen into the probe lumen. The cutter is then withdrawn, transporting the specimen to a tissue collection chamber. Next, the probe, which is still in the breast, is radially rotated in position through a desired angle to align the aperture with another target tissue area. The steps of rotation, cutting, and collection, which can be automated and assisted by vacuum, are repeated until the desired number of samples is obtained.

Although this type of device requires only a small, single incision to obtain a number of core samples, each sample is still limited in size, requiring excision of multiple specimens for accurate pathologic diagnosis. As with other percutaneous excisional devices in which multiple specimens must be obtained, it is often difficult to reconstruct the spatial location and orientation of the suspect tissue as it resided in the breast prior to excision, resulting in a concomitantly difficult pathological analysis.

Another type of percutaneous excisional breast biopsy device designed to first separate healthy tissue from suspect tissue prior to obtaining a single suspect tissue sample is generally described in U.S. Pat. Nos. 5,111,828, 5,197,484, and 5,353,804, the entirety of which are hereby incorporated by reference. This device, however, requires the use of a relatively large diameter cannula to obtain an adequate specimen size.

What is needed is a small-diameter percutaneous excisional biopsy device that allows a physician to obtain, in a minimally invasive manner, a relatively large tissue specimen through a small incision. Further, what is needed is a device that can obtain a specimen large enough for a complete, accurate and satisfactory pathologic determination, obviating the need for obtaining multiple core specimens and reconstructing them ex vivo.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows an assemblage of the components, as in a kit, which make up the inventive tissue removal assembly.

FIGS. **2A** to **2J** show variations of the tissue removal member and their relation to the expandable cutting member.

FIG. **3** shows another variation of the tissue removal member, its associated cutting member, and a desirable manner for transporting the accumulated tissue for later analysis.

FIGS. **4A–4E** show various embodiments of a trocar which fits within the tissue removal member and supports the tissue cutting member as it is introduced into the target tissue region.

FIGS. **5A** to **5C** show perspective, side, and end views of a variation of the cutting member in an expanded configuration together with first and second access members.

FIGS. **6A** to **6C** show perspective, side, and end views of a variation of the cutting member in a collapsed configuration together with first and second access members.

FIGS. **7A** to **7B** show perspective and cross-sectional views of a wire cutting member in an expanded configuration.

FIGS. **8A** to **8B** show perspective and cross-sectional views of a ribbon cutting member, having a leading edge knife-edge cutting surface, in an expanded configuration.

FIGS. **9A** to **9B** show perspective and cross-sectional views of a ribbon cutting member, having a leading edge serrated cutting surface, in an expanded configuration.

Figures **10A** to **10B** show perspective and cross-sectional views of a ribbon cutting member, having a mid-span serrated cutting surface and a leading edge knife-edge cutting surface, in an expanded configuration.

FIG. **11A** is a side view of a typical endoscopic snare suitable for use in grasping the removed tissue in accordance with this invention. FIG. **11B** shows a harpoon spear which is also suitable for accessing and grabbing tissue for use in removing selected tissue when using this device. FIG. **11C** is an expandable braid and optional allied hook also suitable for retrieving tissue using this invention.

FIG. **12** shows a peel-away sheath covering for the expandable tubular tissue removal member.

FIGS. **13A** through **13F** show partial perspective and side views of variations of the invention having a tissue separation member.

FIGS. **14A** through **14F** show a typical procedure sequence using the invention described herein.

DESCRIPTION OF THE INVENTION

As noted above, this invention relates to devices and procedures for removing integral volumes of tissue, typically breast tissue, via percutaneous access. The diameter of the tissue volume removed using this invention is larger than the diameter of the access device. Depending upon the size of the device selected, the inventive device may be used for biopsy samples or for excision of larger amounts of tissue containing "suspicious areas" or tumorous masses. Because of the method in which the device operates, the trauma caused by removal of the chosen volume is significantly lessened as compared to other available devices. This translates to minimized recovery time, little-to-no scarring, lower risk for infection and hemotoma formation, and other advantages when compared to conventional processes. Although the devices and procedures described and claimed herein are preferably utilized in the removal of suspect breast tissue, they are not so limited. These devices may also be effectively used for in number of other areas of the body, such as the liver, the prostate, lymph nodes, and the like. In general, any organ or portion of the body where minimally invasive techniques such as herein described, where a relatively large tissue specimen is obtained through a small incision, is expressly within the scope of this invention. Therefore, the claims herein should be accordingly read.

In general, the procedure involved is this: first, a target tissue mass is selected. A trocar, localization wire, tubular vessel removal member, and a cutting member are assembled and introduced percutaneously to the vicinity of the volume to be removed. The localization wire penetrates through the target tissue mass, and the trocar is withdrawn. The cutting member is positioned to excise a generally cylindrical mass of tissue. The cylinder may be removed as a single specimen after the cutting is completed or during the step of producing the cut. In addition, the tissue may be cut into smaller specimens during the procedure. The step of cutting may be variously assisted by the use of radio frequency (RF) energy, ultrasound, mechanical energy such as cutting, vibrating and rotating, or any combination thereof.

FIG. **1** shows, in generic fashion, the components typically used in the inventive procedure. Tissue removal member (**100**) is shown in FIG. **1** as typically having a single lumen. This lumen is for both the removal of excised tissue

from the targeted body site and for positioning the cutting member (300), as will be discussed below. The trocar (200), which fits within the larger lumen in tissue removal member (100), is also shown. Trocar (200) is used to penetrate the skin and tissue and thereby to position the distal end of the tubular tissue removal member (100) in the region of the tissue volume to be removed.

FIG. 1 shows a typical cutting member (300). Attached to cutting member (300) are two shafts (400) that typically are placed within the smaller lumen of tissue removal member (100). One shaft is typically rotationally fixed, while the other shaft is typically axially rotatable so that cutting member (300) can assume a collapsed, low-profile configuration or, upon axial rotation of one of the shafts (400), the expanded configuration as shown in FIG. 1. Cutting member (300) will generally assume a collapsed configuration (not shown) while in the lumen of tissue removal member (100). As the cutting member shafts (400) and cutting member (300) situated in the lumen of tissue removal member (100) are advanced distally out of tissue removal member (100), the rotatable shaft is rotated to expand the cutting member (300) as it advances, cutting through tissue so that a generally cylindrical or football-shaped mass of tissue is cut at the chosen site. The lesion or tumor is targeted so that it is situated within that chosen cylindrical or football-shaped region.

After cutting the distal end of the tissue specimen to excise it, the tissue is then removed from the body by any number of methods such as, for example, use of a removal member (500) such as that shown in FIG. 1. Desirably, the tissue is placed in tissue collection chamber assembly (600) for later study. Additional tissue specimens can also optionally be removed from the body site if desired. The tissue removal member (100) is then removed from the body site.

Generally, the region to be excised is identified using stereotactic, ultrasonic, or other indexing apparatus as is well known in the art. It is typical that the advancement of the cutting member (300) is controlled using a controller box (700) such as that depicted in FIG. 1.

Tissue Removal Member

FIG. 2A shows a variation of the inventive tissue removal member (100). This variation includes a larger lumen member (102) and a smaller lumen member (104) which is exterior to large lumen member (102). An expandable cutting member (300) is shown attached to shafts (402) and (404) extending from small lumen member (104). Central to this invention is the concept that the cutting member (300) is capable of excising a tissue specimen which is significantly larger in diameter than is the large lumen member (102) of the tissue removal member (100). Tissue removal member (100) can be constructed from any of a large number of polymers typically used in this service, e.g., NYLON, reinforced NYLON, polypropylene, polyethyleneterephthalate (PET), polyesters, polyethylene, fluorocarbon plastics (e.g., TEFLON), etc. The polymers may be reinforced by fibers or filled. As will also be discussed below, the tissue removal member may be reinforced or made radially expandable using coils or braids of metals, alloys, or polymers (natural or synthetic) included in the member. The member (100) or braids may be made at least partially radio-opaque by introduction of, e.g., powdered tantalum, powdered tungsten, bismuth carbonate, and other known particulate and fibrous radio-opacifiers. Radio-opaque markers or crimps may singly or additionally be used on member (100) or the braids to serve this purpose. Tissue removal member (100) may also be partially or entirely coated and possibly cured with coating materials such as high-elongation silicone or room-temperature vulcanizing rubber or the like. Such coatings generally serve to enhance the functionality of tissue removal member (100) without sacrificing its performance characteristics, such as radial expandability.

FIG. 2B shows a similar tissue removal member (110). In this variation, the small lumen tubular portion (112) is not exterior to but is instead within the large lumen member (114). Again, the cutting member (300) is shown attached to two shafts (402), (404) extending from the small lumen tubular member (112).

FIG. 2C shows a more typical variation in which the cutting member (not shown) and its two attendant shafts (402), (404) are disposed in the tissue removal member (120) having only a single lumen member (122). This simple variation is less complex and more suitable for use when the tissue removal member (120) is elastically expandable as described below.

FIG. 2D is a partial cutaway of another variation of the tissue removal member (130). In this variation, the tubular portion (132) of the removal member is elastically expandable. This is depicted by the expanded portion (134) shown in FIG. 2D. An expandable outer tubular section is suitable with any of the variations described above. This variation, however, is expandable due to the use of a woven braid (136) and an elastomeric polymer forming the outer layer (138) of the device. An optional inner layer (140) is also depicted in FIG. 2D but an such inner layer (140) is not, obviously, absolutely necessary. It is convenient and desirable, however.

FIG. 2E is yet another variation of the tissue removal member (140). In this variation, the tubular portion (142) is elastically expandable in the same way as described above. The distal end (144) of tubular portion (142) is, however, attached to cutting member (300), and member (140) is partially covered by sheath (145) as will be described later. Tubular tissue removal member (140) may be attached to cutting member (300) by any conventional means. For instance, they may be joined mechanically or joined integrally from identical, similar, or dissimilar materials, such as metal or plastic. Further, an additional joining member (not shown) may serve to join tubular member (140) to cutting member (300). It is important, regardless of the joining means or method, that cutting member (300) be allowed to expand and contract with rotation of one of the shafts (402) and (404) as will be described in detail later. This embodiment is characterized by the fact that expansion and contraction of cutting member (300) will concomitantly expand and contract the distal end (144) of the tubular tissue removal member (140). In this way, as a tissue specimen is cut by cutting member (300), forward advancement of the cutting member (300) will allow the tissue removal member distal end (144) to assimilate a tissue specimen as tubular portion (142) expands to accommodate the tissue specimen as it is excised. Such a design enables the device to be fully operable without the use of a removal member (500) (not shown), as the entire device may be pulled from the body once the tissue specimen is inside lumen (146) of tubular portion (142). This does not mean, however, that the embodiment of FIG. 2E cannot be used with a removal member (500); for instance, such a removal member can be used to assist removing tissue through the proximal end of tissue removal member or when multiple tissue specimens are to be removed without having to remove the entire assembly from the body.

FIG. 2F depicts another variation. Here, the first and second access members, or shafts, (402) and (404), are

attached to the tubular tissue removal member (140) in the general proximity of the removal member (140) distal end (144).

The distal end (144) of member (140) can be split in a direction parallel to the longitudinal axis of member (140), creating a longitudinal aperture (148), or gap, and two attendant edges (150) and (152) in tissue removal member (140). This aperture (148) may extend partially down the length of member (140) as shown in FIG. 2F, or completely, as shown in FIG. 2G. In either case, shafts (402) and (404) may be attached, temporarily or permanently, to tissue removal member (140) in the vicinity of edges (150) and (152). In the case where aperture (148) is partial, as shown in FIG. 2F, shafts (402) and (404) will align with edges (150) and (152) at the distal end (144) of tissue removal member (140), and run generally parallel to edges (150) and (152), diverging slightly as edges (150) and (152) merge at vertex (154).

In the embodiment of FIG. 2G, where the gap (148) exists the entire length of tissue removal member (140), the shafts (402) and (404) can be connected at edges (150) and (152) or at least substantially parallel to the edges. However, it is within the scope of the invention that shafts (402) and (404) need not be so configured with respect to edges (150) and (152) for the device to work properly.

As will be described in greater detail, one of the shafts (402), or access members, is preferably rotatably fixed. Likewise, the other shaft (404) is preferably axially rotatable so that it may expand and collapse cutting member (300), and in the case of the FIGS. 2E–2G embodiments, some or all of tissue removal member (140). The entire device may also be axially rotatable about the tissue removal member (140) longitudinal axis (not shown).

In the FIG. 2F embodiment, the aperture (148) acts to facilitate collapse of cutting member (300) in that rotation of shaft (404) will also collapse tissue removal member (140) so that the aperture (148) reduces in size as edges (150) and (152) move closer, meet, or even substantially overlap along all or a portion of their length. Expansion of cutting member (300) and tissue removal member (140) by axial rotation of access member (404) in the opposite direction, as explained in detail later, will likewise act to expand member (140), widen aperture (148), and move edges (150) and (152) further apart.

When gap (148) takes on the form shown in FIG. 2G, rotation of shaft (404) will uniformly cause tissue removal member to collapse in a manner similar or identical to cutting member (300), such that edges (150) and (152) close aperture (148) by moving together as edge (152) collapses in on itself (FIG. 2H) or, alternatively or in conjunction with the movement described immediately above, the entire edge (152) is translated to close aperture (148) and move edge (152) closer to, or overlap, edge (150) (FIG. 2I). This complex movement of edges (150) and (152) by axial rotation of access member (404), translation of access member (404) with edge (152), singly and in combination with one another or with rotation and translation of the entire assembly, in conjunction with cutting member (300), provides a wide variety of configurations and tissue excision capabilities, the entirety of which are within the scope of this invention.

Shafts (402) and (404) may be fixed, temporarily, removably or permanently to tissue removal member (140) in a wide variety of configurations, such as in the lumen (146) side of member (140), on the exterior side of member (140), and within the structure of member (140) as described, for instance, in conjunction with FIG. 2D. As long as shaft (404) is rotatable as herein described, and shaft (402) is fixed as herein described any attachment configuration is acceptable.

FIG. 2J shows a dual-ring configuration in which an aperture (148) exists as described above. A second ring (340) is fixed to the distal end (144) of tubular tissue removal member (140) as described above for the cutting ring (300); however, ring (340) is not for excising tissue. This second ring (340) provides a removable attachment site for cutting member (300) so that tubular portion (142) may expand and contract with cutting member (300) as described herein. Second ring (340) may have its own shafts (not shown) or may be attached to shafts (402) and (404) of ring (300). Ring (340), when used with radio frequency cutting, may be insulated with any acceptable means, such as a coating, or inherently by virtue of its composition, to insulate tissue removal member (140) from RF energy. Aperture (148) can be partial (shown) or full (not shown).

The embodiment of FIGS. 2A–2J may be used with radio frequency cutting, mechanical cutting, ultrasound cutting, or any combination thereof. The relatively large aperture (148) shown in FIGS. 2F, 2G and 2J is obviously exaggerated for purposes of clarification.

Tissue Collection Chamber Assembly

FIG. 3 shows another variation of the inventive tubular tissue removal member (160). Of particular instance in this variation is the presence of a receiver, or tissue collection chamber assembly (162) situated at the proximal end of the tubular tissue removal member assembly (164).

Of special interest is the tissue collection chamber, or specimen collector (166) which may be fitted within tissue collection chamber assembly (162). The position of the tissue cutting member (300) can be indexed with the position of the tissue collector (166) so that as the tissue is removed through the tubular tissue removal member (164), it ultimately resides in the tissue collection chamber (166) in the very position as found in the chosen collection site within the body. A cap (168) for the tissue collection chamber (166) is also shown.

Tissue collector (166), which can accommodate the various instruments herein described, can also be marked as appropriate for indicating the orientation of the tissue specimen. For instance, either or both distal end (174) or proximal end (176) of the collector (166) or cap (168) may be marked with words such as "top", "bottom", "front" and "rear" or the like; symbols may be used as well. Likewise, one or more sides of the collector (166) may be marked to indicate tissue orientation as shown in FIG. 3. Although not shown, cap (168) could alternately be located on the opposite end of collector (166), or collector (166) could have two caps.

Additionally, a label (170) may be placed on the tissue collector (166) to indicate particular information about the specimen, the patient, or the conditions of the procedure; e.g., identification number/name of patient, physician, date of procedure, left or right breast, special instructions, etc.

Tissue collection chamber assembly may have at least one port (172) to accommodate the various instruments herein described, as well as a tissue specimen. Port (172) is aligned with tissue collection chamber (166) so that a tissue sample may enter chamber (166) therethrough. Either or both distal or proximal ends (174) and (176) of chamber (166) may define a port (172) for the same purpose as described above.

Either or both tissue collection chamber assembly (162) and tissue collection chamber (166) may be partially or wholly transparent to x-ray or other energy so that the instruments and tissue specimens may be visible therethrough.

Trocar And Localization Wire

The trocar used in this assemblage is preferably one which fits within the inner lumen of the tubular tissue removal member. This permits the trocar to carry that member as it penetrates the outer skin and the tissue on the pathway to the selected site. The trocar used in this invention may simply be one having a sharp mechanical cutting surface or may be connected to one of any of known RF sources which generates energy for cutting tissue and, perhaps, cauterizing it as the initial incision is made.

FIGS. 4A shows a typical, but desirable, variation of a trocar (200) which is especially suitable for use in this assembly. Specifically, trocar (200) has a sharp leading pointed end (202), a sharp cutting edge (204) and, desirably, two longitudinal grooves (206) and (208) extending along a portion or all of the exterior surface (210) of trocar (200). Grooves (206) and (208) are sized to accommodate shafts (402) and (404) (not shown) when trocar is extended through tissue removal member (140) so that a low-profile configuration may be accomplished to allow deployment of trocar (200), shafts (402) and (404), and cutting member (300) (not shown) in a smooth fashion.

Additionally, trocar (200) may contain one or more transverse slots (212) for carrying the cutting member to the selected tissue site. Slot (212) can extend partially along exterior surface (210) of trocar (200), in conjunction with another slot, or extend completely around trocar (200) to hold the entire cutting ring (300).

FIGS. 4B–4C show another desirable variation of trocar (200). Here, the trocar (220) contains two longitudinal grooves (226) and (228) along with slots or grooves (230) for carrying cutting ring and its shafts as described above.

However, trocar (200) additionally contains an aperture (232) defined in the interior of the trocar along the trocar longitudinal axis (234). This aperture (232) is for the containment and passage therethrough of a localization wire (240).

Localization wire (240) is used as conventionally known to locate the tissue lesion or specimen to be excised during the initial phase of the excision process. Localization wire (240) is preferably made from titanium, nickel, stainless steel, tantalum, tungsten, or cobalt, and alloys thereof, and more preferably stainless steel or a nickel-titanium alloy. Wire (240) preferably has a diameter of between about 0.005 inch to about 0.050 inch, and more preferably has a diameter of between about 0.010 inch and about 0.025 inch (aperture (232) is sized to accommodate wire (240)). If not comprised of a radiopaque material, wire (240) is at least partially radiopaque. Radiopaque distal tip (242) facilitates tissue location and assists the physician user in operating the inventive device.

Wire (240) can extend proximally through a tissue removal member, collection chamber and assembly, and even through a controller box or drive unit (700) for automated or manual manipulation. Wire (240) is freely axially moveable within trocar (200) and the other devices described above.

Slightly different slots (230) are shown in FIGS. 4B–C for accommodating cutting member (300). Also shown are four cutting edges (204) for separating tissue.

FIGS. 4D–E show a desirable configuration for trocar (200). Here sharp cutting edges consist of a collapsible blade (234) which is biased, by a spring or any other suitable means (not shown), to assume an extended, deployed position for cutting tissue. This extended position will be the natural position for the blade (234) when the trocar (200) is extended distally out the distal end (144) of tubular tissue removal member (140).

Upon proximal retraction of trocar (200), as shown in FIG. 4E, blade (234) proximal end (236) will engage distal end (144) of tissue removal member (140) and force blade (234) to retract into trocar (200) and lock against an optional locking pin (238) (or other suitable means such as a notch or latch) into trocar (200), allowing trocar (200) to further move proximally into tissue removal member (140). Likewise, distal movement of trocar (200) out distal end (144) of member (140) frees blade (234) to assume its biased, deployed position as shown in FIG. 4D. Locking pin (238) is not necessary for the operation of the trocar (200) of FIGS. 4D–E; blade (234) can stay retracted entirely by engagement with distal end (144) of member (140).

Trocar (200) can be made partially or entirely of stainless steel, nickel, titanium, cobalt, tungsten, or alloys thereof. In addition, proximal end (238) of trocar (200) can be optionally made of any suitable biologically inert plastic and joined to the distal end by any suitable means.

Access and Cutting Members

The cutting members discussed herein are all similar in that each have a cutting surface, i.e., the portion of the device which meets the tissue and cuts a path whether that path is made by a mechanical cutting as with a knife blade or if the separation is made by an RF or ultrasound energy source. The cutting member may be attached to an RF or ultrasound source or may be made up of mechanical cutters or may be combinations of those. Often, the members are mechanically vibrated or rotated to produce a cutting motion. The tissue itself can also be vibrated to produce a differential motion between the tissue and the cutting surface to create a mechanical cutting motion.

FIGS. 5A–5C show perspective, side, and end views, respectively, of a particularly useful configuration for cutting member (300) and access members (402) and (404) where the cutting member (300) is in its expanded condition. Specifically, FIG. 5A shows a ribbon cutting member (300) fixed at each of its first (302) and second ends (304) to shafts, or access members (402) and (404). Cutting member (300) may be affixed to access members (402) and (404) by any suitable means, such as welding, soldering, brazing, adhesive or mechanical fastening means such as crimping and the like; likewise, cutting member (300) may be integrally formed with access members (402) and (404) so as to preclude the need for joining them together.

Access members (402) and (404) may comprise a shaft, wire or rod (as shown in FIGS. 5 and 6), hollow or solid, or they may take other forms as suitable for achieving their intended purpose as described in detail below. Access members may be fabricated from various alloys, such as stainless steel, or metals such as titanium, platinum, tantalum, cobalt, nickel, other suitable biologically inert metals or their alloys. Especially desired are radiopaque materials, such as stainless steel or platinum and its alloys. In addition, access members (402) and (404) may also comprise biologically inert polymeric or organic materials or mixtures thereof. If access members (402) and (404) comprise a metal or metal alloy, it is desirable that one or both members be fully or partially coated with, or inserted within, a polymeric layer or member. Such a layer serves to insulate the access members (402) and (404) from RF energy if it is utilized.

When compared to FIGS. 5A–5C, FIGS. 6A–6C illustrate the desired operation of access members (402) and (404) in

conjunction with cutting member (300). First access member (402) is desirably, though not necessarily, rotatably fixed so that it is not capable of rotation about its longitudinal axis (406). This may be accomplished in a variety of ways. For instance, it may be manually held from rotating by the physician user, or it may be permanently or releasably fixed in controller box (700) or other suitable apparatus. As a result of being fixed, first access member (402) acts to hold the first end (302) of cutting member (300) fixed in space with respect to the first access member longitudinal axis (402). This provides a reference point upon which the physician user may rely to accurately place the tissue removal assembly, and most importantly, cutting member (300), at the precise location of the tissue to be excised.

Second access member (404) desirably is free to rotate about its longitudinal axis (408). The axial rotation of second access member (404) may be accomplished and controlled in a variety of ways, the scope of which is not limited by the following examples. For instance, axial rotation may be directly controlled manually by the physician user, or it may be indirectly controlled via controller box (700). Such a control device could be activated manually, hydraulically, or electronically, for instance, by a dial, button, switch, or the like. Such a control device preferably allows the physician user to incrementally control the degree of axial rotation of second access member (404) depending on a variety of factors such as the preferred diameter of the tissue sample to be cut, as will be discussed in greater detail below.

As shown in FIGS. 6A–6C, axial rotation of second access member (404) results in a likewise rotation of the second end (304) of cutting member (300), to which the distal end of second access member (404) is affixed. As rotation continues beyond 360°, second end (304) of cutting member (300) continues to turn in with respect to the first end (302) such that the diameter D (FIG. 5C) of cutting member (300) is effectively reduced to D' (FIG. 6C). The degree of rotation is limited only by the physical limits imposed by cutting member (300), so that theoretically second access member (404) may rotate through several complete or partial turns, resulting in a tightly wound and constricted cutting member (300), whose diameter D' is now notably smaller than its original diameter D.

The rotatability of second access member (404) and, in turn, second end (304) of cutting member (300) is critical to the cutting action of the tissue removal assembly, especially in cutting off a distal end of the tissue specimen, such as when the device is used with RF energy.

Although it is desirable that first access member (402) be fixed as described above, first access member (402) can also be free to rotate about its longitudinal axis (406) in the same manner as described above with respect to second access member (404). In this manner, it is desirable that second access member (404) likewise be rotatably fixed about its longitudinal axis (408) as described above. However, it is not absolutely necessary that one access member be rotatably fixed while the other is not; both access members can simultaneously be rotatably fixed or both may be free to rotate about their respective longitudinal axes.

Further, when not attached to tubular tissue removal member (140), both first and second access members (402) and (404) are, independently or jointly, moveable in all other directions and modes, such as axial translation in a direction parallel to their respective longitudinal axes, lateral translation in any direction not parallel to the same axes, or rotation about any orthogonal axis (not shown), for example. This allows for free movement of the independent components of the tissue removal assembly by the physician user during operation.

Finally, independent of any of the capabilities mentioned above, both first and second access members (402) and (404) are jointly axially rotatable about an axis (410) defining the center of the cutting ring (300). As the device is moved forward to the distal end of a tissue specimen, this capability allows the physician user to rotate the entire assembly so to assist them in cutting off the distal end of the tissue specimen and excising it from the body.

Turning now to the cutting member (300), FIGS. 7–10 depict exemplary configurations for a cutting member (300) that can be used to cut the desired tissue sample by RF energy, ultrasound energy, mechanically, or any combination thereof.

FIGS. 7A and 7B depict a simple configuration where the cutting member (302) has a generally round cross-section. When this configuration is used, the cutting member may be a solid or hollow wire, shaft, rod, ribbon, or other shape approximating a generally round, oval, or square cross section. This configuration is especially suitable for RF cutting.

FIGS. 8A and 8B depict a ribbon cutting member (304) having a generally rectangular cross section and a single knife-edge cutting surface (306). This cutting surface (306) assists in cutting tissue upon rotation and axial translation of cutting member (304) with respect to the tissue to be excised. When used in conjunction with RF energy, a sharpened knife edge cutting surface (306) will focus the RF energy towards the leading edge of the cutting surface and facilitate movement of the device through the tissue and to cut off the distal end of the tissue specimen. Cutting surface (306) can be on either side of cutting member (304).

FIGS. 9A and 9B show a ribbon cutting member (308) having a generally rectangular cross-section and a serrated cutting surface (310) that may be particularly useful in combination with a rotating action or vibratory cutting when in conjunction with RF or ultrasound energy. This further limitation of surface area on the leading edge of the cutting member enhances the use of RF energy in the cutting member of the inventive device. Serrated cutting surface (310) can be on either side of cutting member (308).

FIGS. 10A and 10B show a cutting member (312) having an optional serrated cutting surface (316) extending in a direction generally perpendicular from the surface of the cutting member (312). This serrated cutting surface (316) can be used to assist in cutting tissue in a plane generally perpendicular to the length of the tissue specimen, especially as the cutting member (312) is expanded by the rotation of second access member as previously described. Such a cutting surface (316) can also be a smooth knife-edge, and can be used in conjunction with one or more cutting surfaces, such as knife-edge cutting surface (314). Although not shown in FIGS. 10A and 10B, a similar serration can additionally or singly exist on the opposite interior surface (318) of cutting member (312).

The ribbon cutting member (300), although shown in FIGS. 8–10 as having some type of knife-edge or serrated cutting surface, need not have such a cutting surface at all. This is especially true when cutting member (300) is used with RF energy to cut through tissue. In addition, other cross-sectional shapes and cutting surface configurations may be used in the tissue removal assembly.

The material making up the cutting members shown in FIGS. 7 through 10 is not central to this invention. The

materials may be any of a variety of stainless steels, cobalt, tungsten, titanium, nickel, tantalum, and other alloys typically used in this service.

Nonetheless, we have found that certain nickel-titanium alloys are particularly suitable for use with this device, due to the requirement that cutting member (300) be capable of performing under the conditions of repeated expansion and contraction by high radius of curvature bending (i.e. rolling and unrolling the device) via axial rotation of second access member (404) without inducing strain upon the cutting member material. This is also particularly true when the blades are used either as simple knife edge cutters or as a combination of RF/mechanical cutters. This material is typically a 50/50 molar ratio alloy of titanium and nickel; however, other ratios are within the scope of the invention. Closely related alloys are the shape memory alloys which exhibit superelastic/pseudoelastic shape recovery characteristics. These alloys are well-known and are commonly referred to as "nitinol." See, for instance, U.S. Pat. Nos. 3,174,851, 3,351,463, and 3,753,700, the entirety of which are hereby incorporated by reference. These alloys are characterized by their ability to be transformed from an austenitic crystal structure to a stress-induced martensitic (SIM) structure at certain temperatures, and return elastically to the austenitic shape when the stress is removed. These alternating crystalline properties provide the alloy with its super-elastic properties. The nitinol forms of these alloys are readily commercially available and typically will undergo the austenite-SIM-austenite transformation at a variety of temperature ranges between -20° C. and 30° C.

Tissue Manipulation Devices

FIGS. 11A through 11C show tissue manipulation devices as may be used in conjunction with the overall assembly. In some instances, it may be desirable to grasp the initial portion of excised tissue so to guide it through the tissue removal member. Depending on which of the configurations of tissue removal member is selected, a choice of one of the noted devices may be appropriate.

FIG. 11A shows a simple endoscopic grasping device (500) which is readily available on the commercial market. Movement of the scissor-like handle produces a corresponding movement on the grasping tongs (504).

FIG. 11B shows a tissue manipulation device (506) having a small wire-like shaft (508) and a harpoon-like end (510). For the purposes of completeness only, a manipulation knob (512) is also included for view.

FIG. 11C shows a combination of a braided grasper (520) and a hook component (522). The braided tissue snaring device (520) includes a distal woven braid section (524) which is easily manipulated by the two control wire or rods (526) and (528). If necessary, hook (522) is used to pull the excised tissue into braided cage (524) or to push the braided cage over the excised tissue. The two control wires (526) and (528) are used to either expand the diameter of braided cage (524) or to make that diameter smaller. Once the tissue is at least partially within the braided cage (524), the device is removed from the lumen of the tissue removal device.

Other devices for removing excised tissue from the selected site, such as vacuum or suction assisted removal, would certainly be appropriate.

Peel-Away Sheath

A desirable but optional feature of the present invention is shown in FIG. 12 as sheath (600). Sheath (600), in its most general sense, is a thin covering or tube designed to fit over the exterior surface of expandable tubular tissue removal member (602) and to hold member (602) in a collapsed, non-expanded position prior to excision and removal of tissue. This ensures tissue removal member (602) maintains a low profile during the tissue accession steps. Sheath (600) also acts to provide additional axial, longitudinal, and torsional rigidity to member (602). Sheath (600) may be used with any of the designs herein described. Sheath (600) is desirably comprised of a biologically inert polymer; accordingly it can comprise any of the materials described herein or their equivalents.

Preferably, sheath (600) contains at least one perforation (612) running along all or a portion of the length of sheath (600) in a direction parallel to the sheath longitudinal axis (606) from its proximal end (608) towards its distal end (610). Perforation (612) allows the physician user to remove, or peel away, sheath from tissue removal member (602) during use so that member (602) may radially expand. An optional handle (614) is located at or near the proximal end of sheath (600) to facilitate removing, or peeling away, sheath (600) at perforation (612).

Tissue Separating Member

FIGS. 13A–13B shows an optional tissue separating member (800) spanning the diameter of the distal end (804) of expandable tubular tissue removal member (802). Separating member (800) desirably is extensible such that when tissue removal member (802) is in a radially collapsed position, as shown in FIG. 13A, it bends or collapses to assume a first position. This position is not important; i.e., it may be due to separating member containing foldable joints, taking on a spring form, or bowing in a proximal or distal direction with respect to tissue removal member distal end (804), as long as separating member (800) is capable of performing its function described below.

FIG. 13B shows separating member (800) in a second, extended or expanded configuration where it is generally straight as it spans the tissue removal member distal end (804) diameter. This is the position achieved when tubular tissue removal member is radially expanded. In all the embodiments, separating member (800) can take the form of a spring, hollow or solid wire or rod, a ribbon or ribbon-like braid, etc. It may be comprised variously of any of the metals or alloys herein described, although it is preferably comprised of a nickel-titanium alloy. Separating member (800) is used in the following manner with any of the variations of the inventive device described herein: as tissue removal member (802) and/or cutting ring is moved forward to excise a tissue specimen, the distal end (804) approaches the tissue specimen. Rather than assimilating the entire tissue specimen whole into the tissue removal member (802), it may be desirous to further cut the tissue specimen into two or more additional pieces so that each or all may be sequentially or simultaneously removed from the body. Separating member (800) accomplishes this by cutting the tissue specimen as it passes proximally through the distal end of tissue removal member (802).

Accordingly, separating member (800) may comprise a mechanical blade with one or more sharp cutting surfaces, it may be attached to an RF energy source via a wire (not shown) or the fixed access member described above, it may be attached to an ultrasound energy source, a mechanical vibration or oscillation source, or any combination thereof. Separating member (800) can even be connected to a manual or automated deploying force so to assist its expansion from the first, collapsed configuration to the second, expanded configuration.

Tissue separating member is shown in FIGS. 13A–13B as a single member obviously only capable of cutting an excised tissue specimen into two separate pieces and rotating at the tissue distal end to excise the tissue from the body. It is within the scope of the present invention for the separating member to contain any number of additional members for cutting the tissue specimen into three or more pieces. An example of this is shown in FIG. 13C, wherein separating member (806) comprises a plurality of cutting elements (808) connected at distal pivoting connecting point (810). FIG. 13C shows this embodiment in a collapsed configuration while FIG. 13D shows member (806) in its second, expanded configuration. An optional cutting surface (812) on distal end (804) can also be used to cut tissue.

FIGS. 13E and 13F, respectively, show collapsed and expanded versions of separating member (800) without any tissue removal member. This is a simple yet desirable configuration, in which separating member (800) is connected at each end to the distal end of access members (402) and (404).

In all its embodiments, tissue separating member (800) may be used in conjunction with the ring cutting member (300) or alone to achieve the desired result of excising and cutting a tissue specimen, including rotating to cut the tissue specimen distal end, from the body. Member (800) may be used variously with or without RF energy. In addition, tissue may be pulled proximally through separating member (800) to separate or cut tissue as opposed to pushing the device distally through the tissue.

Controller Box

As shown generically in FIG. 1, controller box or driver unit (700) is a preferable component of the present invention. In addition to the functions described above, controller box may serve various other functions such as providing a source of RF energy, a source of ultrasound energy, a source of mechanical energy, and the like. Mechanically, controller box (700) provides variously for rotation, translation, and vibration of cutting member (300), expansion and contraction of ring (300) and/or tubular tissue removal member (100). It serves as a connecting site for the variously described energy sources to the inventive device, and can be automated to any desirable degree to assist the physician user to properly and safely use the invention. As generically described, it is appreciated that controller box (700) may additionally contain other features or perform other functions as necessary for the proper and safe use of the invention. An example of a device having such functions is found in U.S. Pat. No. 5,526,822, which is hereby incorporated by reference.

Procedure for Use

FIGS. 14A through 14F show a generic method for using the tissue removal assembly of this invention. For the purposes of illustration, this description assumes that the user is removing a lesion found in breast tissue. The lesion (900) is found behind skin surface (902). Surrounding tissue is also shown. The generic device found in FIG. 1 is used for purposes of this description with the exception that tissue removal member (100) is in a simpler configuration consisting of only a single, expandable tubular member and that cutting member (300) is attached to the distal end of tissue removal member (100). The use, however, according to this invention is not significantly different when other variations of the device are used.

FIG. 14A shows the assembled device ready for introduction to the skin surface. Shown is the expandable tissue removal member (100) and trocar (200) with the attached cutting member and attached first and second access members (shown in dashed lines) not yet inserted in the proximal end of the tissue removal member (100). The device is positioned at the skin surface so that when the cutting member and expandable tissue removal member (100) expanded to its full diameter by axial rotation of second access member, the lesion (900) is within a circumference corresponding to that diameter. Tip (242) of localization wire (240) is also shown extending from trocar (200).

FIG. 14B shows the assembled device after localization wire (240) has been extended completely through the lesion (900) under stereotactic guidance, and the trocar (200), tissue removal member (100) with cutting member and access members have penetrated the skin surface (902) and are approaching lesion (900).

FIG. 14C shows the initial expansion of the collapsed cutting member (300) and the distal end of tissue removal member (100). This variation shows the use of an RF powered cutting member (300). A mechanical or ultrasound cutter may obviously be employed as well or instead of an RF-style cutter (300). The cutting member (300) and removal member (100) is first extended to the section of tissue distal to the lesion through the path cut by trocar (200) in a collapsed configuration. RF power is then applied to the cutting member (300), which is next rotated by a rotatable access member, after removal of optional sheath (600) (not shown), so to form a circular cut distal to lesion (900). This circular cut will be the end of the cylinder of tissue which is ultimately removed.

FIG. 14D shows axial movement of the cutting member (300) and the generally cylindrical tissue mass (904) formed as the cutting member (300) is simultaneously optionally rotated until the cutting member (300) is past lesion (900) during application of RF energy.

FIG. 14E shows the collapsing and simultaneous rotation of cutting member (300) by axial rotation of second access member (404) during application of RF energy so to cut the tissue distal to lesion (900) and allow the physician user to remove the newly formed cylindrical tissue mass (904) surrounding lesion (900) from the breast.

FIG. 14F shows the introduction of grasping member (400) to the distal end of the cylindrical tissue mass (904) containing lesion (900) and the removal of the cylindrical tissue mass (904) through the lumen of tissue removal member (100). In this instance, tissue removal member (100) is braided and radially expandable so to accommodate a tissue mass (904) which has a significantly larger diameter than its own diameter. This is a particularly attractive feature of the invention that obviates the need for making a large incision to remove a relatively large tissue mass (904). The tissue mass (904) may be cut into two or more additional pieces as it enters the tissue collection chamber by one or more tissue separating members (not shown).

The entire assembly may then be removed from the incision or may be used to excise additional tissue from the site. Note that the tissue volume depicted in FIGS. 14A–F is generally football-shaped as is appropriate. However, especially when used with RF, a tissue specimen shape generally approximating a right cylinder is possible.

Ultrasound energy may also be utilized to assist in the cutting action of the cutting member (300). For instance, a source of ultrasound energy may be included in controller box (700), for instance, and selectively transmitted, alone or in conjunction with mechanical or RF-assisted cutting, to vibrate the cutting member (300) and surrounding tissue to facilitate cutting the tissue sample.

When used solely or in conjunction with mechanical cutting or ultrasound, RF energy may be utilized in the frequency range of about 500 Hz to about 500 KHz to assist in cutting the desired tissue. The appropriate power setting, frequency, and waveform may be selectively chosen by the physician user or automatically preset or selectable through controller box (700) or any commercially available RF controller device.

Alternatively, or in addition to RF cutting, RF energy can be selectively used to cauterize the cut tissue in the remaining cavity in the vicinity of the excision margin to minimize trauma, control unnecessary bleeding, and to prevent hemotoma formation. An example of the use of RF energy for such an application is more thoroughly described in U.S. Pat. Nos. 5,085,659, 5,569,244 and 5,578,030, the entirety of each hereby incorporated by reference. This can be done not only during the tissue accession and removal steps, but after the tissue specimen is removed from the body. In addition to or instead of using the present inventive device for such cautery, any typical electrocautery probe as is well-known in the art may be used.

Prior to, during, or after such cauterization, the remaining cavity may be examined with an endoscope or other appropriate viewing device so to assist the user physician in locating bleeders. Once the physician user is satisfied that the remaining cavity is properly cauterized, the cavity may be alternatively packed with appropriate biologically inert packing material, such as a fibrin-collagen matrix, to further prevent unnecessary bleeding, minimize the possibility of hemotoma formation, and to help prevent dimpling or deformation of the breast.

The entire procedure can be accomplished while the patient is under local anesthesia. The device is capable of being utilized stereotactically or under ultrasound guidance. In addition, the device is capable of computer control so that even more precise operation may be accomplished.

The invention herein has been described by examples and a particularly desired way of practicing the invention has been described. However, the invention as claimed herein is not loaded to that specific description in any manner. Equivalence to the description as hereinafter claimed is considered to be within the scope of protection of this patent.

We claim as our invention:

1. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing to a position adjacent a selected internal tissue region, a trocar, a localization wire, an expandable tissue removal member having an enclosing sheath, and a cutting member, the cutting member movable between a collapsed first position and an expanded second position,

b) inserting the localization wire through the selected internal tissue region,

c) withdrawing the trocar from the position adjacent the selected internal tissue region,

d) removing the enclosing sheath from the tissue removal member,

e) moving the cutting member to cut a discrete tissue mass in the selected internal tissue region having a diameter generally greater than the expandable tissue removal member, and

f) removing the discrete tissue mass through the tissue removal member.

2. The procedure of claim 1 where the enclosing sheath is partially removed.

3. The procedure of claim 1 where the enclosing sheath is completely removed.

4. The procedure of claim 1 where the cutting member is a radio frequency cutter.

5. The procedure of claim 4 where the radio frequency cutter further comprises a mechanical blade.

6. The procedure of claim 1 where the cutting member is a mechanical blade.

7. The procedure of claim 6 further including the step of vibrating the mechanical blade cutting member.

8. The procedure of claim 6 further including the step of rotating the mechanical blade cutting member.

9. The procedure of claim 6 where the cutting member is an ultrasound cutter.

10. The procedure of claim 6 where the tissue removal member is a braided, expandable tubular member.

11. The procedure of claim 6 further including the step of placing the discrete tissue mass in a tissue collection chamber.

12. The procedure of claim 11 further including the step of delivering the tissue collection chamber containing the discrete tissue mass to a laboratory for analysis.

13. The procedure of claim 6 further including the step of further cutting the discrete tissue mass into one or more smaller pieces.

14. The procedure of claim 6 wherein the discrete tissue mass is generally cylindrical.

15. The procedure of claim 6 wherein the discrete tissue mass is football-shaped.

16. The procedure of claim 6 further comprising the steps of:

(g) moving and advancing the cutting member to cut a second discrete tissue mass,

(h) removing the second discrete tissue mass, and

(i) removing the expandable tissue removal member.

17. The procedure of claim 6 wherein step (f) comprises using a tissue manipulation device to assist removing the discrete tissue mass through the proximal end of said expandable tissue removal member.

18. The procedure of claim 6 wherein the discrete tissue mass is not penetrated by the cutting member.

19. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing, to a position adjacent the selected internal tissue region, a tissue removal assembly, said assembly comprising:

a cutting member moveable between a collapsed first position and an expanded second position, the cutting member having a first end, a second end, and at least one cutting surface,

a first access member having a longitudinal axis, a proximal end, and a distal end, the distal end of which is fixed to the first end of the cutting member, and a second access member having a longitudinal axis, a proximal end and a distal end, the distal end of which is fixed to the second end of the cutting member; the second access member axially rotatable about the longitudinal axis so that axial rotation of the second access member will move the cutting member between the collapsed first position and the expanded second position,

b) moving the cutting member to cut a discrete tissue mass in the selected internal tissue regional, and

c) removing the discrete tissue mass.

20. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing, to a position adjacent the selected internal tissue region, a cutting member attached to two shafts and movable between a collapsed first position and an expanded second position,

b) moving the cutting member longitudinally with respect to the shafts to cut a tissue mass in the selected internal tissue region, and

c) removing the tissue mass.

21. The procedure of claim **20** where the cutting member is a radio frequency cutter.

22. The procedure of claim **21** where the radio frequency cutter further comprises a mechanical blade.

23. The procedure of claim **21** where the cutting member is a mechanical blade.

24. The procedure of claim **23** further including the step of vibrating the mechanical blade cutting member.

25. The procedure of claim **23** further including the step of rotating the mechanical blade cutting member.

26. The procedure of claim **20** where the cutting member is an ultrasound cutter.

27. The procedure of claim **20** further including the step of placing the tissue mass in a tissue collection chamber.

28. The procedure of claim **27** further including the step of delivering the tissue collection chamber containing the tissue mass to a laboratory.

29. The procedure of claim **20** further including the step of further cutting the tissue mass into one or more smaller pieces.

30. The procedure of claim **20** further including the step of introducing a tissue removal member to a position adjacent the selected internal tissue region.

31. The procedure of claim **30** wherein the tissue mass is removed through the tissue removal member.

32. The procedure of claim **30** wherein the tissue mass has a diameter generally greater than a diameter of the tissue removal member.

33. The procedure of claim **30** where the tissue removal member is a braided, expandable tubular member.

34. The procedure of claim **20** wherein the tissue mass is generally cylindrical.

35. The procedure of claim **20** wherein the tissue mass is football-shaped.

36. The procedure of claim **20** wherein the position adjacent the selected internal tissue region is proximal of the selected internal tissue region.

37. The procedure of claim **20** wherein the tissue mass is not penetrated by the cutting member.

38. The procedure of claim **20** wherein at least steps (a) through (b) are performed under stereotactic x-ray guidance.

39. The procedure of claim **20** wherein at least said steps (a) through (b) are performed under ultrasound guidance.

40. The procedure of claim **20** additionally comprising the step of cauterizing the tissue surrounding a cavity remaining after removing the tissue mass.

41. The procedure of claim **20** additionally comprising the step of packing a tissue cavity with biologically inert packing material, said cavity remaining after removing the tissue mass.

42. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and an expanded second position,

b) moving the cutting member to cut a single discrete integral tissue specimen in the selected internal tissue region.

c) removing the tissue specimen, and

d) packing a tissue cavity with biologically inert packing material, said cavity remaining after the removing the tissue specimen.

43. The procedure of claim **42** wherein said packing material comprises a fibrin-collagen matrix.

44. The procedure of **42** wherein said packing material is inserted to prevent unnecessary bleeding.

45. The procedure of **42** wherein said packing material is inserted to minimize the possibility of hematoma formation.

46. The procedure of **42** wherein said packing material is inserted to help prevent dimpling or deformation.

47. A procedure for removing tissue from a selected internal tissue region in a patient's breast, comprising the steps of:

a) introducing an expandable percutaneous tissue removal device into the patient's breast,

b) using the device to cut tissue in the selected internal tissue region,

c) removing the cut tissue, thereby creating a tissue cavity, and

d) preventing dimpling or deformation of the breast by packing the tissue cavity with inert packing material, wherein the inert packing material comprises a fibrin-collagen matrix.

48. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and expanded second position, wherein the cutting member is a radio frequency cutter further comprising a mechanical blade, and tissue removal member,

b) moving the cutting member to cut a discrete tissue mass in the selected internal tissue region, wherein the tissue mass has a diameter generally greater than the diameter of the tissue removal member, and

c) removing the tissue mass through the tissue removal member.

49. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and an expanded second position, and a tissue removal member, wherein the tissue removal member is a braided, expandable tubular member,

b) moving the cutting member to cut a discrete tissue mass in the selected internal tissue region, wherein the tissue mass has a diameter generally greater than the diameter of the tissue removal member, and

c) removing the tissue mass through the tissue removal member.

50. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and an expanded second position, and a tissue removal member,

b) moving the cutting member to cut a discrete tissue mass in the selected internal tissue region, wherein the tissue mass has a diameter generally greater than the diameter of the tissue removal member,

c) removing the tissue mass through the tissue removal member, and

d) packing a tissue cavity with biologically inert packing material, said cavity remaining after removing the tissue mass.

51. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) making an incision in a skin region in proximity to the selected internal tissue region;

b) introducing, through the incision, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and an expanded second position, wherein the cutting member is a radio frequency cutter further comprising a mechanical blade;

c) moving the cutting member to cut a discrete tissue mass in the selected internal tissue region, wherein the diameter of the discrete tissue mass is larger than the size of the incision; and

d) removing the tissue mass through the incision.

52. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) making an incision in a skin region in proximity to the selected internal tissue region;

b) introducing, through the incision, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and an expanded second position,

c) introducing a tissue removal member to a position adjacent the selected internal tissue region tissue region.

d) moving the cutting member to cut a discrete tissue mass in the selected internal tissue region, wherein the diameter of the discrete tissue mass is larger than the size of the incision and wherein the discrete tissue mass has a diameter generally greater than the diameter of the tissue removal member; and

e) removing the tissue mass through the incision.

53. The procedure of claim **52** where the tissue removal member is a braided, expandable tubular member.

54. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) making an incision in a skin region in proximity to the selected internal tissue region;

b) introducing, through the incision, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and an expanded second position,

c) moving the cutting member to cut a discrete tissue mass in the selected internal tissue region, wherein the diameter of the discrete tissue mass is larger than the size of the incision,

d) removing the tissue mass through the incision; and

e) packing a tissue cavity with biologically inert packing material, said cavity remaining after removing the tissue mass.

55. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and an expanded second position, wherein said cutting member is oriented about an axis,

b) axially moving the cutting member along the axis to cut a single discrete integral tissue specimen in the selected internal tissue region, and

c) removing the tissue specimen.

56. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and an expanded second position, wherein the cutting member is a radio frequency cutter further comprising a mechanical blade,

b) moving the cutter member to cut a single discrete integral tissue specimen in the selected internal tissue region, and

c) removing the tissue specimen.

57. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

a) introducing, to a position adjacent the selected internal tissue region, a cutting member movable between a collapsed first position and an expanded second position,

b) introducing a tissue removal member to a position adjacent the selected internal tissue region wherein the tissue removal member is a braided, expandable tubular member,

c) moving the cutting member to cut a single discrete integral tissue specimen in the selected internal tissue region, and

d) removing the tissue specimen.

* * * * *

US006375661B2

(12) **United States Patent**
Chu et al.

(10) **Patent No.: US 6,375,661 B2**
(45) **Date of Patent: *Apr. 23, 2002**

(54) **APPARATUS FOR SEVERING AND CAPTURING POLYPS**

(75) Inventors: **Michael S. H. Chu**, Brookline; **Yem Chin**, Burlington, both of MA (US)

(73) Assignee: **Boston Scientific Corporation**, Natick, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/730,771**

(22) Filed: **Dec. 7, 2000**

Related U.S. Application Data

(60) Continuation of application No. 09/457,700, filed on Dec. 9, 1999, now Pat. No. 6,171,315, which is a division of application No. 09/146,105, filed on Sep. 3, 1998, now Pat. No. 6,010,512, which is a division of application No. 08/421,409, filed on Apr. 13, 1995, now Pat. No. 5,846,248.

(51) **Int. Cl.**[7] **A61B 17/32**
(52) **U.S. Cl.** **606/113**; 606/114
(58) **Field of Search** 606/113, 114, 606/46, 110, 47

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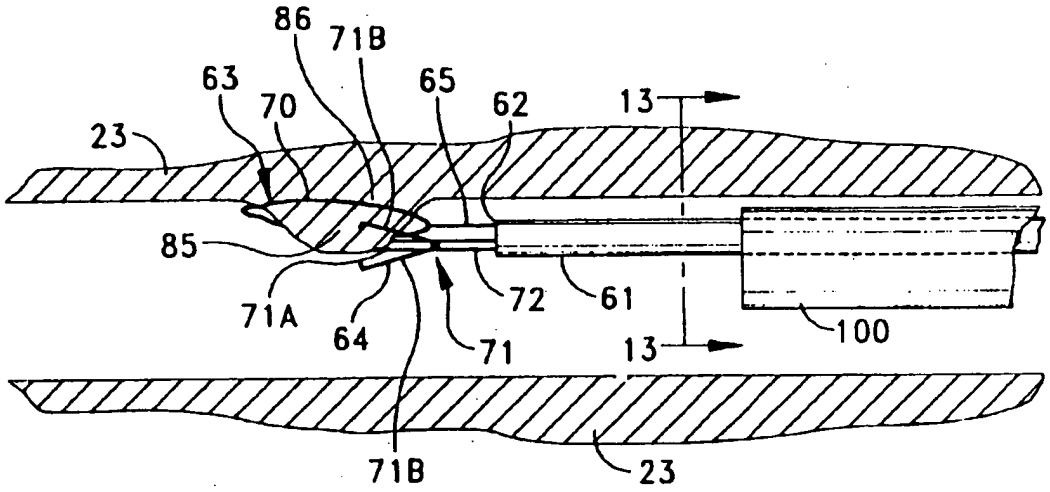
Primary Examiner—Michael H. Thaler
(74) *Attorney, Agent, or Firm*—Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

(57) **ABSTRACT**

A method and apparatus for managing polyps by which an elongated tubular member is generally positionable within the working channel of an endoscopic device. The tubular member carries a selectively extendable severing device and capturing device at its distal end. Control apparatus at the proximal end of the tubular member enables a physician to extend and retract the severing and capturing devices. The physician retracts the capturing device to grasp the portion of the polyp to be severed and retracts the severing device to sever the polyp. The capturing device retains the severed portion of the polyp for removal with the tubular member. In one embodiment, the capturing device includes an injection needle.

10 Claims, 7 Drawing Sheets



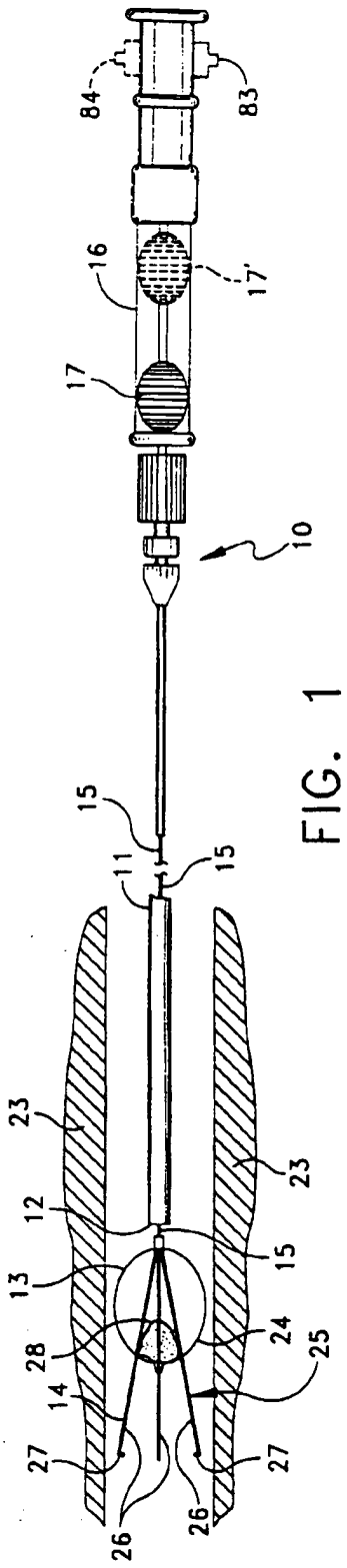


FIG. 1

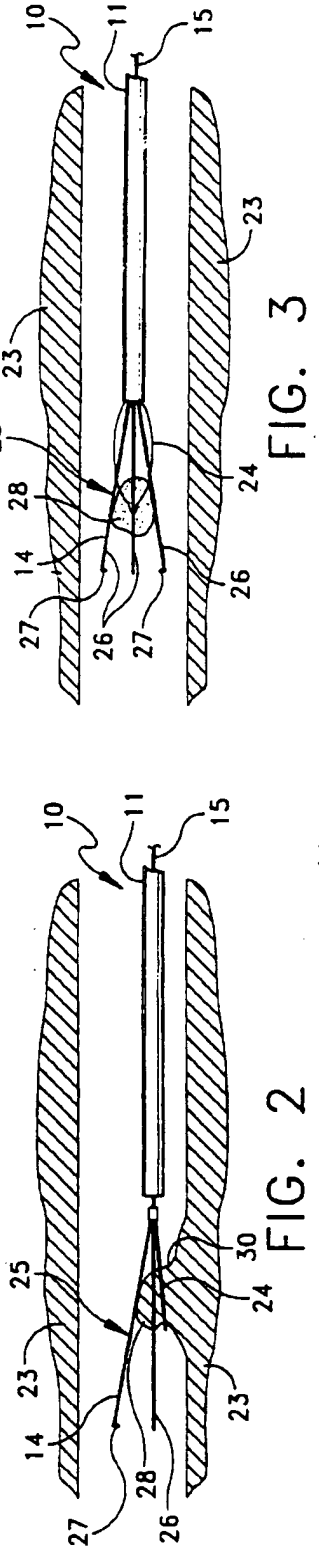


FIG. 3

FIG. 2

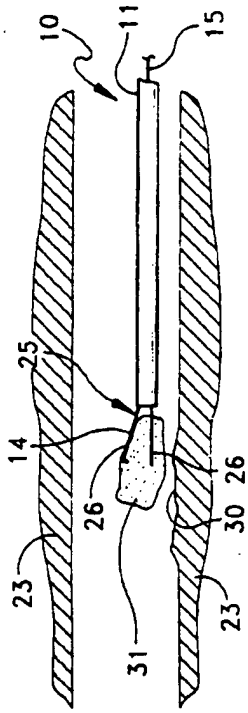


FIG. 4

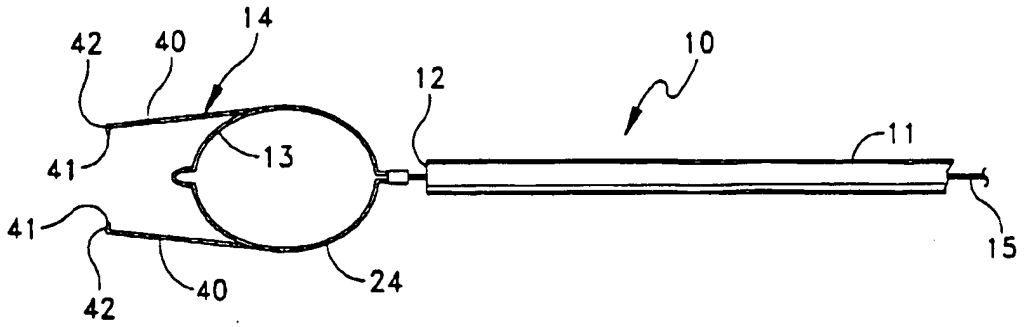


FIG. 5

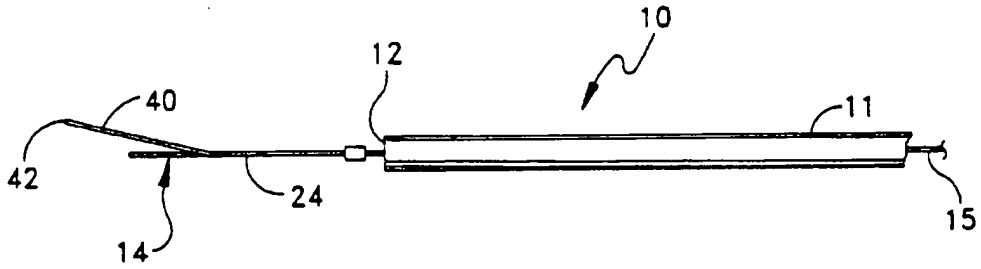
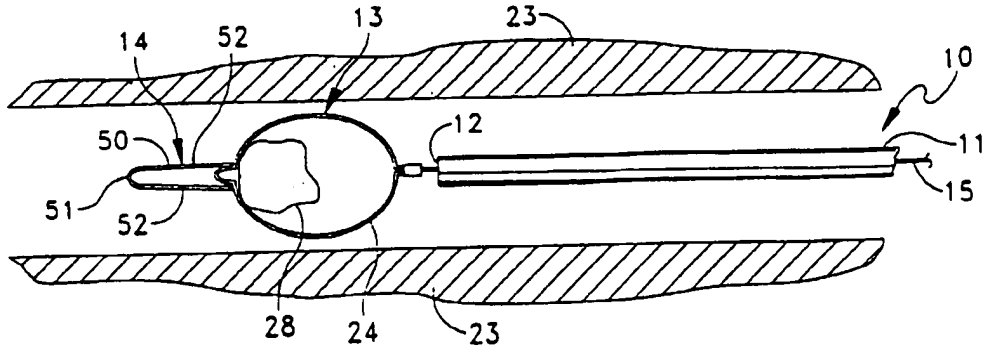


FIG. 6



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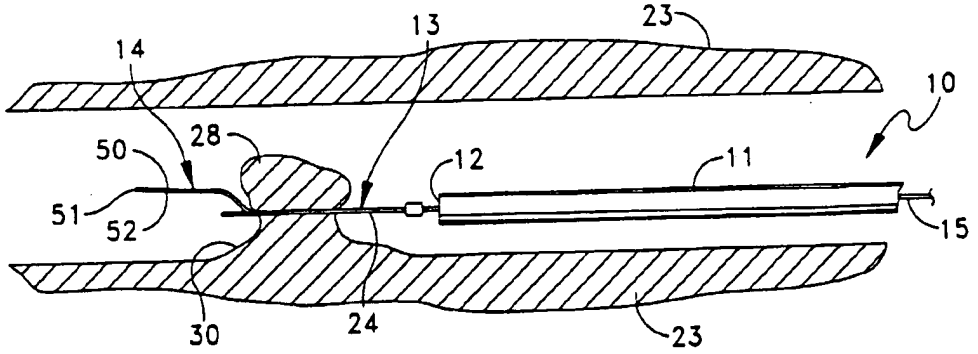


FIG. 8

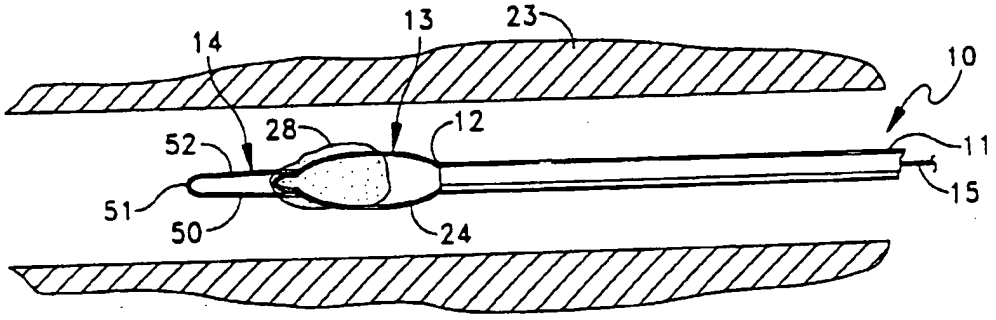


FIG. 9

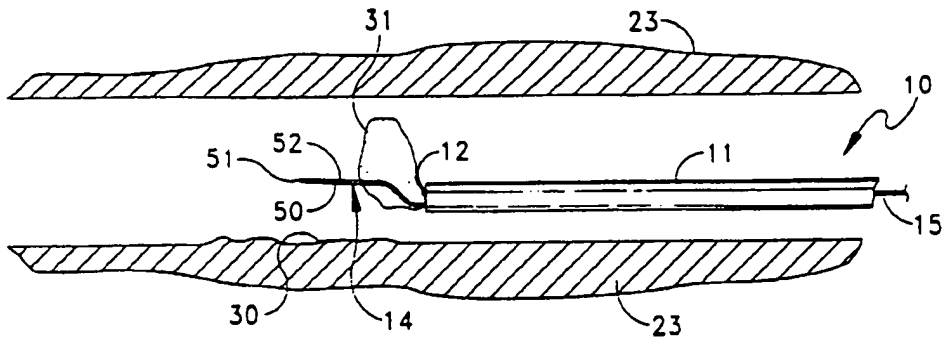


FIG. 10

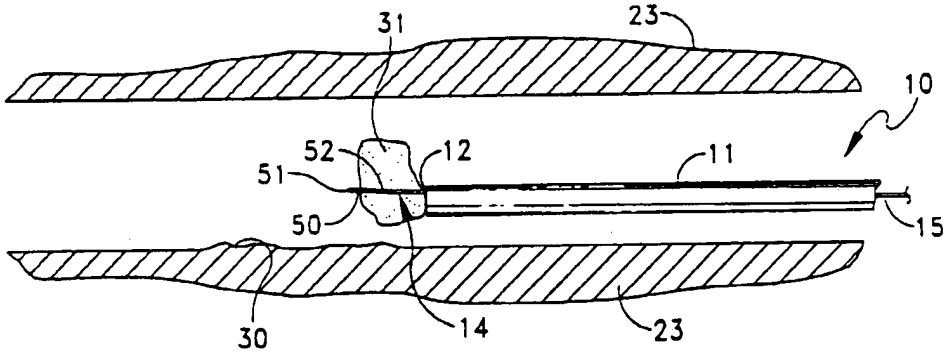


FIG. 11

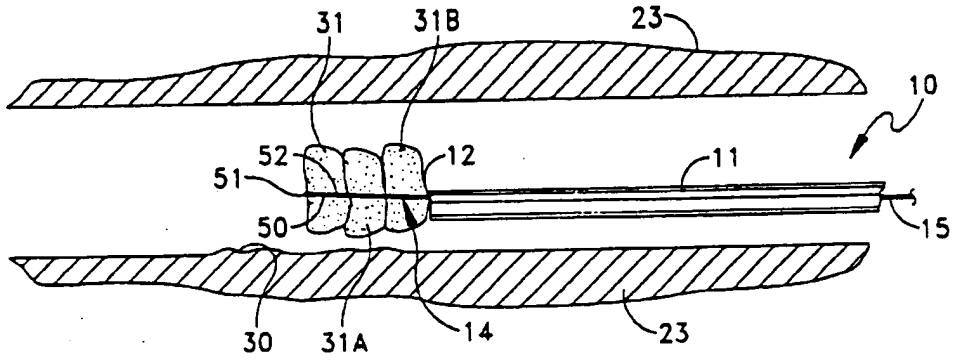


FIG. 11A

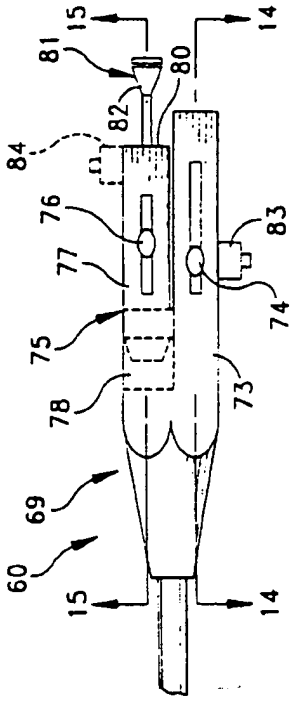


FIG. 12

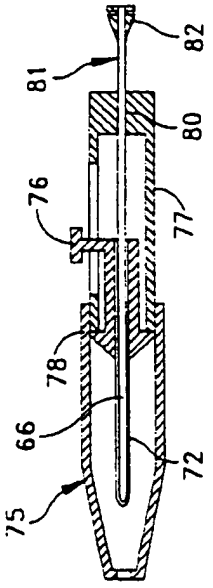


FIG. 15

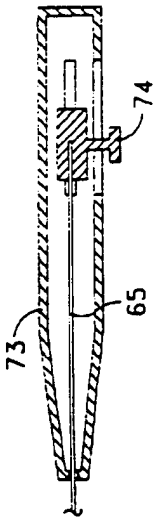
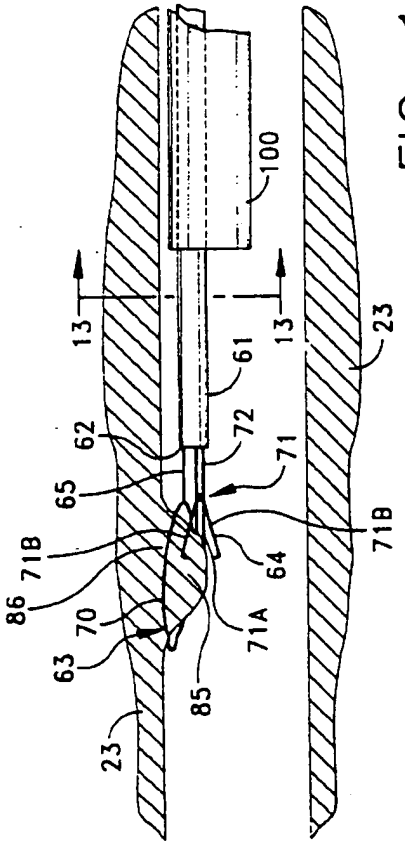


FIG. 14



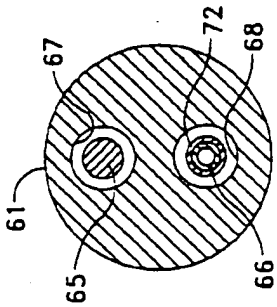


FIG. 13

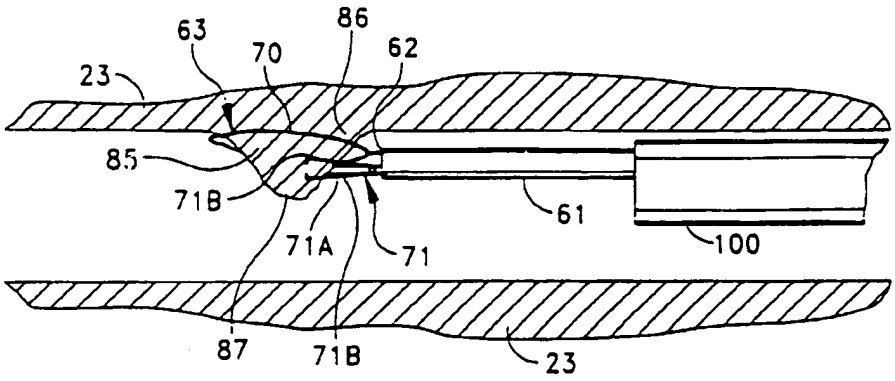


FIG. 16

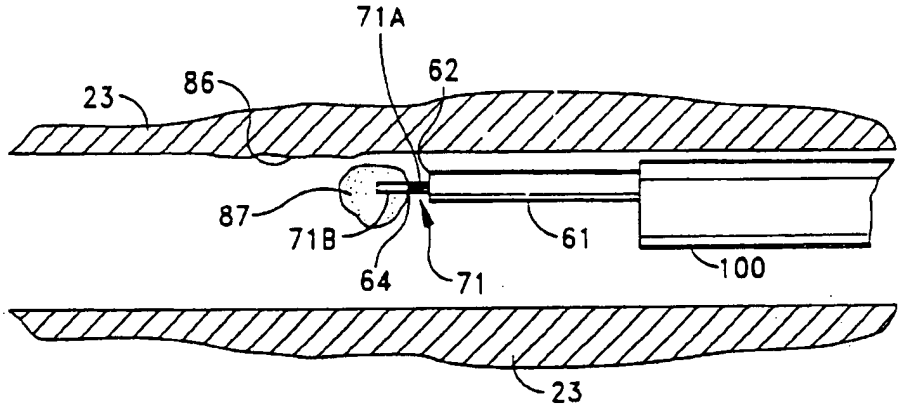


FIG. 17

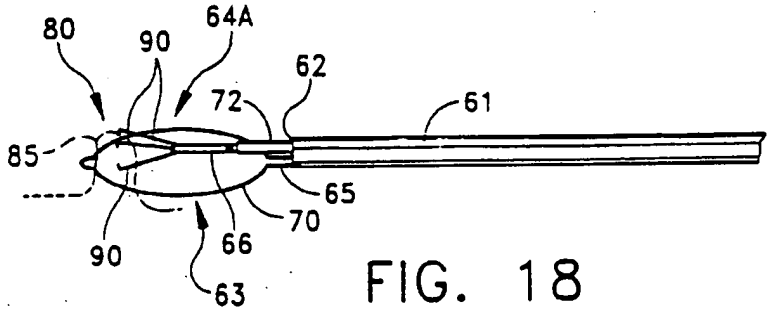


FIG. 18

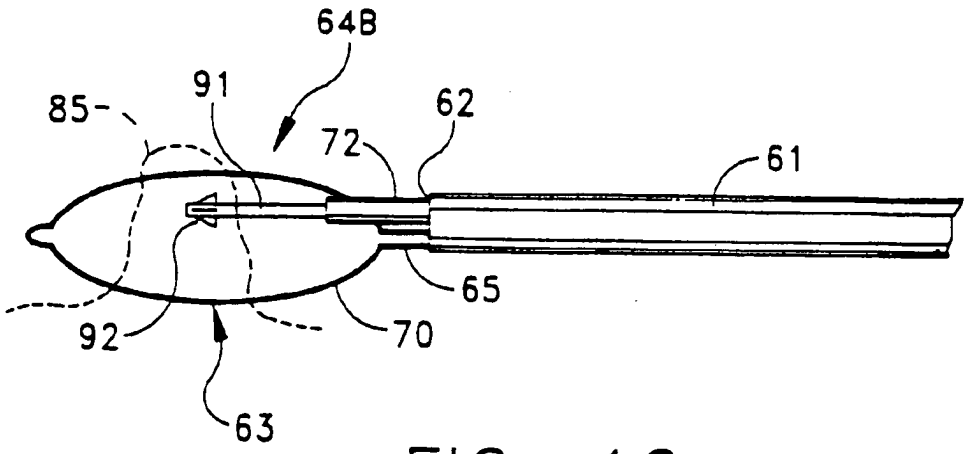


FIG. 19

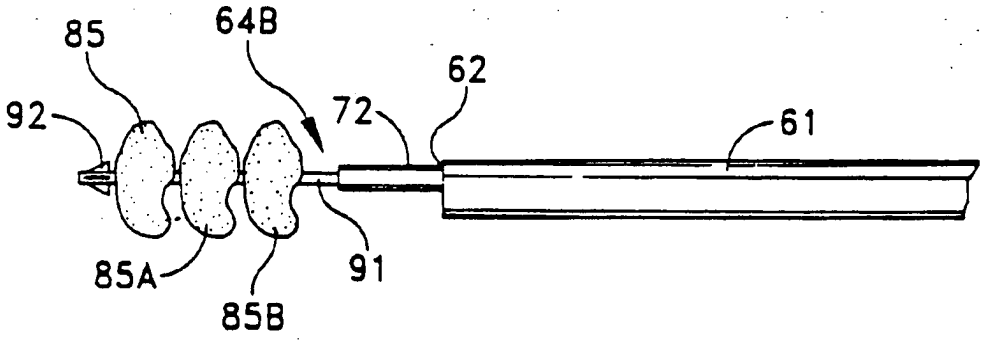


FIG. 19A

APPARATUS FOR SEVERING AND CAPTURING POLYPS

This is a continuation of application Ser. No. Pat. No 09/457,700, filed Dec. 9, 1999, now U.S. Pat. No. 6,171,315 which is a division of application Ser. No. 09/146,105, filed Sep. 3,1998, now Pat. No 6,010,512, which is a division of application Ser. No. 08/421,409, filed Apr. 13, 1995, now U.S. Pat. No. 5,846,248, all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to surgical apparatus and methods for polyp management and more particularly to such apparatus and methods for severing and capturing polyps.

2. Description of Related Art

The treatment of polyps and other similar growths in a patient has improved greatly within the last several decades. Polyps are generally collected for histopathological evaluation to determine if they are cancerous. Initially the primary method of treating polyps was major surgery. Now polypectomy procedures are based upon the insertion of a surgical catheter through the working channel of an endoscope. Polypectomy procedures have essentially replaced surgical procedures except when polypectomy procedures are deemed unsuitable, such as when the polyp or polyps to be removed are relatively planar in nature. As used in this application, an endoscope includes endoscopic or other similar device that is inserted into a patient and that includes a working channel for receiving a surgical catheter or the like and a viewing channel for viewing the interior of a vessel.

The following United States Letters Patent disclose surgical apparatus for polyp management procedures:

U.S. Pat. No. 5,122,147 (1992) Sewell, Jr.

U.S. Pat. No. 4,326,530 (1982) Fleury, Jr.

Sewell, Jr. discloses several embodiments of a polyp marking device and method of using them. FIG. 4 illustrates three generally concentric loops extending from the distal end of the housing. Spacing members contact each loop thereby to position the loops along radially inner, outer and underneath paths. The inner loop **20** has one end fixed to the housing and rachets onto a polyp proximate its base by retraction of a second end extending distally through the housing. The outer loop **23** retracts to grasp the polyp proximate its free end. An intermediate cutting loop has one end fixed in the housing and severs the polyp by retraction of a second end extending through the housing. The inner loop **20** remains attached to the base of the severed polyp.

In another embodiment disclosed by Sewell, Jr. retraction of a cutting loop **21** severs an inner loop **20** from a housing. After such retraction, a forceps device is inserted through the distal end of the housing. Manipulation of the forceps device enables a physician to capture the severed portion of the polyp. Other embodiments disclosed by Sewell, Jr. disclose clamping devices or jaws having one or more cutting edges for severing a polyp whereby the jaws close to return the severed portion of the polyp. Sewell, Jr. avoids the use of an electric current for cauterizing the severed base by applying a hemostatic agent to the base of the polyp from the inner loop.

Fleury, Jr. discloses a surgical instrument for removing cellular tissue from body cavities. The instrument includes a proximal handle and a distally extending tubular member. A cable passes through the tubular member and includes a

self-expanding loop or snare at its distal end. Extension and retraction of the cable enables the loop to enlarge and encompass a polyp and then contract to and sever the polyp. The loop conducts rf electrical current to cauterize the stump of the severed polyp. However, the catheter of Fleury, Jr. does not provide apparatus associated with the instrument itself for capturing the severed portion of the polyp. Rather Fleury, Jr. suggests that other suitable means such as suction associated with a colonscope equipment (i.e., an endoscopic device) captures the severed portion.

Another type of known surgical catheter for performing polypectomy procedures includes a loop or snare disposed at the distal end of the catheter. A basket or net connects to the loop along its defined arc. In use the basket overlies the portion of a polyp to be severed by the loop. Thus, upon severing of the polyp the basket captures the severed portion.

The advantages of such prior art polypectomy procedures in contrast to major surgery are numerous. The advantages generally include reductions in the time and trauma of the operation itself, the time of recovery of the patient, the risk of infection and other problems associated with major surgery. Thus, a surgical catheter device of the prior art generally includes a tubular member extensible through the working channel of an endoscopic device with a cutting loop positioned at the distal end of the tubular member and may include a mechanism for cauterizing the base of a severed polyp.

However, prior art polypectomy devices sometimes are unsuitable for treating certain polyps and are cumbersome and often extend the duration of a procedure unnecessarily.

Some embodiments disclosed by Sewell, Jr., for example, require the use of a separate forceps instrument used in conjunction with the disclosed instrument to retrieve the severed polyp. Generally, Sewell, Jr. discloses a device which requires multiple control wires, three wires in the case of the embodiment of FIG. 4. Furthermore, Sewell, Jr. leaves the inner loop within the body of the patient so that it must be retrieved or otherwise passed from the patient's body.

The device disclosed by Fleury, Jr. also has limited usefulness because it does not include any apparatus for grasping the severed portion. Although some endoscopic devices use suction to extract tissue, the suction, at acceptable levels, is frequently insufficient to hold a severed polyp at the end of the device. Using suction also requires positioning the distal end of the endoscope proximate the polyp. This is not always a simple task. It frequently requires a high degree of skill and dexterity. Should the polyp not be held, it is often difficult to retrieve the severed polyp. Using a forceps device to retrieve such severed portion usually requires the removal of the surgical catheter from the working channel of the endoscope device and insertion of the forceps device. The snare and basket arrangements offer the possibility of retrieving several polyps without removing the apparatus from a patient. However, the weight of the basket depending from the snare tends to deflect the snare and the distal end of the surgical instrument. Consequently it can be difficult to maneuver the snare over a selected polyp. The loops of the basket overlying the snare also can impede snare closure and severance of a selected polyp. Moreover, the movement of the basket loops along the snare tends to dull the snare and makes the severing more difficult. The baskets, being metallic, can contact the snare and bypass current used for cauterizing the severed stump of the polyp. Also, in the case where multiple polyps are collected there is no means to adequately associate the particular polyps collected with the location from which such polyps were taken.

The prior art taken collectively, thus fails to provide an easily used and simply constructed surgical apparatus for effectively and reliably severing and capturing polyps at diverse shapes and sizes. There is no suggestion of a method and apparatus for efficiently and effectively capturing a polyp or severing and capturing successive ones of such polyps in a reliable manner and, additionally, being able to associate the position from which such polyps were taken with particular polyps. Further, the prior art devices which require repeated removal and insertion to take a plurality of polyps generally also require repeated removal and insertion of the endoscope, because polyps frequently are larger than the working channel of such endoscopes. Thus, the repeated insertion and removal increases the time for such polypectomy procedures and associated trauma to the patient.

SUMMARY

Therefore, it is an object of the present invention to provide a surgical apparatus for effectively and reliably severing and capturing a polyp.

Another object of this invention is to provide a surgical apparatus that is simple to manufacture and use and that efficiently and effectively captures and severs a polyp.

Still another object of this invention is to provide a method for managing polyps that enables a physician to efficiently and effectively remove polyps from a patient.

Yet another object of this invention is to provide a surgical apparatus having a holding device and a severing device positioned at a distal end of the apparatus that are independent of each other.

Yet still another object of this invention is to provide a surgical apparatus having a control mechanism for concurrent extension and retraction of a holding device and a severing device positioned at a distal end of the apparatus.

Still yet another object of this invention is to provide a method for severing and capturing a polyp that includes the step of positively holding the polyp prior to severing such that the severed portion of the polyp is captured.

Yet a further object of this invention is to provide a method and apparatus for enlarging a polyp to promote severing and for capturing a polyp.

Still yet a further object of this invention is to provide a method and apparatus for successive severing and capturing of polyps within a patient prior to removal of the apparatus.

A further object of this invention is to provide a method and apparatus for retaining severed and captured polyps in an order corresponding to the order of such severing and capturing.

According to one aspect of this invention apparatus for severing and retaining a polyp includes an axially extending catheter with a distal end that can be positioned proximate a polyp. A self-expansible severing and capturing device is extensible from the distal end in an expanded form and is retractable into the catheter in a compacted form. Actuation of a control device at a proximal end of the catheter externally of the patient enables extension and retraction of the severing and capturing device relative to the distal end of the catheter thereby to enable polyp removal.

According to another aspect of this invention a surgical instrument, adapted for use in the working channel of an endoscopic device and for capturing and severing a portion of a polyp, includes an elongated tubular member extending proximally from a distal end and a snare carried by the tubular member for encompassing and severing a polyp. Selective extension of a holding device carried by the tubular member independently of the snare holds the polyp proximate its free end so that upon severing of the polyp the holding device retains the severed portion of the polyp.

According to yet another aspect of this invention a surgical instrument for severing and capturing a polyp includes an elongated tubular member proximally extending from a distal end and adapted to extend through the working channel of an endoscopic device with a viewing channel. The tubular member supports a snare for extension in an enlarged condition and retraction in a compact condition relative to the distal end. Control apparatus enables a physician to selectively extend and retract the snare. A capturing device connects with the control apparatus for extension and retraction with the snare so that upon retraction the capturing device grasps and retains a portion of the polyp severed by the snare.

According to a further aspect of this invention a method for managing polyps in a patient includes locating a catheter proximate a selected polyp. Extension of a self-expansive severing device from the catheter encompasses the polyp proximate its base. Extension of a holding device from the distal end of the catheter upon maneuvering engages the polyp proximate a free end thereof. Retracting the severing device into the catheter severs the polyp proximate the polyp's base; the holding device retains the severed portion that includes the free end.

According to yet a further aspect of this invention a method for managing polyps in a patient includes locating a catheter proximate a select polyp. Extension and orientation of a severing and holding device from the catheter includes encompassing the polyp with a severing portion of the device and a holding portion of the device engaging the polyp proximate a free end thereof. Retraction of the severing and holding device severs the polyp with the holding portion of the device retaining a separate portion including the free end of the selected polyp.

BRIEF DESCRIPTION OF THE DRAWINGS

The appended claims particularly point out and distinctly claim the subject matter of this invention. The various objects, advantages and novel features of this invention will be more fully apparent from a reading of the following detailed description in conjunction with the accompanying drawings in which like reference numerals refer to like parts, and in which:

FIG. **1** is a plan view of a surgical instrument constructed in accordance with this invention having a severing and holding device at a distal end portion for location within a patient proximate a polyp;

FIG. **2** is a enlarged side elevation of a distal end portion of FIG. **1**;

FIG. **3** is a enlarged plan view of the distal end portion of FIG. **1** with the severing and holding device in partially retracted position;

FIG. **4** is a enlarged plan view of the distal end portion of FIG. **1** with the severing and holding device in a retracted position with the polyp severed at is base and the severed portion retained by the holding device;

FIG. **5** is an enlarged plan view of the distal end portion of another surgical instrument in accordance with this invention;

FIG. **6** is an enlarged side elevation of the distal end portion of the embodiment of FIG. **5**;

FIG. **7** is an enlarged plan view similar to FIG. **5** of the distal end portion of another surgical instrument in accordance with this invention;

FIG. 8 is a side elevation of the distal end portion of FIG. 7;

FIG. 9 is a plan view of the embodiment of FIG. 7 with the severing and holding device in a partially retracted position;

FIG. 10 is a plan view of the embodiment of FIG. 7 with a severing portion of the severing and holding device retracted into the tubular member;

FIG. 11 is a plan view of the embodiment of FIG. 7 with the distal portion of a holding portion of the severing and holding device retracted proximate the distal end of the tubular member;

FIG. 11A is a view of the embodiment of FIG. 7 similar to FIG. 11 with the distal portion of the holding portion having a plurality of severed polyps retained therein;

FIG. 12 is a side elevation of a yet another surgical instrument constructed in accordance with this invention with a severing device and a holding device in an extending position relative to a tubular member;

FIG. 13 is a cross-section of the tubular member of FIG. 12 taken along the line 13—13;

FIG. 14 is a cross-section of the handle portion of FIG. 12 taken along the line 14—14;

FIG. 15 is a cross-section of the handle portion of FIG. 12 taken along the line 15—15;

FIG. 16 is a side elevation of the distal portion of FIG. 12 with the holding device and the severing device partially retracted into the tubular member;

FIG. 17 is similar to FIG. 16 with the severing device retracted and the holding device retracted proximate the distal end of the tubular member;

FIG. 18 is a perspective view of a distal portion of yet still another surgical instrument in accordance with this invention;

FIG. 19 is a perspective view of a distal portion of a further surgical instrument in accordance with this invention; and

FIG. 19A is the view of FIG. 19 with a plurality of severed polyps retained on the retaining portion of the device and with the severing portion retracted.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

As depicted in FIG. 1, apparatus 10 for managing polyps according to this invention includes a radially flexible, axial stiff elongated catheter or tubular member 11 extending proximally from a distal end 12 with a severing device 13 and a capturing device 14 extensible from and retractable relative to the distal end 12. The severing device 13 and the capturing device 14 connect at their proximal ends to a cable 15 that extends through the catheter 11 to a handle 16. The cable 15 in this embodiment connects to a slide member 17 suitably supported in the handle 16, although alternatively the cable can be fixed to the handle 16 with the slide member 17 connecting to the tubular member 11. Those skilled in the art will appreciate that displacement of the slide member 17 enables a user to selectively control the distal extension and proximal retraction of the severing device and the capturing device relative to the distal end 12.

FIGS. 1 through 4 illustrate the use of the present invention which is preferably used with a known endoscopic device having a working channel and a viewing channel. The severing device 13 in this embodiment is formed as a snare 24, and the capturing device 14 comprises forceps 25 with distally extending legs 26 secured to the snare extending from the distal end of the cable 15. Each of the legs 26 includes an inwardly extending portion 27 at its free or distal end.

In use, a physician inserts the distal end 12 through the working channel of an endoscope and uses the viewing channel to position the distal end 12 proximate a polyp 28. Once the severing and capturing devices 13 and 14 are extended relative to the distal end 12, the physician maneuvers the severing device 13 to encompass the polyp 28 proximate its base 30. The proper maneuvering of the severing device also positions the capturing device 14 as illustrated in FIGS. 1 and 2. The physician then retracts the cable 15 relative to the distal end 12 by moving the slide member 17 (FIG. 1) from its distal position toward the position 17' to displace the severing and capturing device 13 and 14 into the tubular member 11. As depicted in FIG. 3, retraction of the severing device 13 and the capturing device 14 causes the severing device 13 to close and sever a portion 31 of the polyp 28 and concurrently to urge the severed portion 31 into engagement between the legs 26. Thus, after the severing of the polyp 28 the severed portion 31 is retained by the capturing device 14 so that it can be removed from the patient as the tubular member 11 is withdrawn.

FIGS. 5 and 6 depict an alternative embodiment including a severing device 13 and a capturing device 14. In this case the capturing device 14 comprises two leg members 40 extending from opposed central portions of the snare 24 to define a plane intersecting the plane of the snare 24. Retraction of the severing device 13 and the capturing device 14, once positioned so that the severing device 13 encompasses a polyp 28 with the capturing device 14 disposed proximate the free end of the polyp 28, urges the leg members 40 toward each other so that the portion 31 of the polyp 27 to be severed from the base 30 is grasped or gripped by the leg members 40 enabling retention and removal of the polyp from the patient. Each of the leg members 40 may also include a radially inwardly extending projection 41 proximate free ends 42 to capture the severed portion 31 in a positive fashion.

FIGS. 7 through 11 depict another embodiment of this invention that includes a severing device 13 and a capturing device 14 that are formed as a snare 24 and a collar or clip 50, respectively. The clip 50 has a closed distal end 51 with legs 52 extending proximally therefrom. The legs 52 attach to opposed central portions of the snare 24 so that the clip lies outside the plane defined by the snare 24. In using this embodiment, a physician positions the snare 24 to encompass a polyp 28 proximate its base and the clip 50 opposite the base 30 of the polyp 28. Retraction of the snare 24 into the tubular member 11, as depicted in FIGS. 9 and 10, severs the polyp 28 and urges the severed portion 31 into the clip 51. Further retraction, as depicted in FIG. 11 urges the severed portion 31 into a secure position against the distal end of the clip 51. It will be appreciated by those skilled in the art that providing a collar or clip of sufficient distal extension for receiving a plurality of polyps will enable the removal of such polyps prior to removal of the apparatus 10 from the patient's lumen 23.

The embodiment of FIG. 7 thus enables the grasping and retention of a plurality of polyps. The plurality of retained polyps will be arranged sequentially with the distal most polyp corresponding to the first sample sequentially with the proximal most polyp being the last polyp captured. Thus, the polyps will be stacked in the clip in the order of severing. Specifically each polyp is urged distally in the clip 50, as the cable 15 is retracted to bring the distal end 51 of the clip 50

proximate the distal end 12 of the tubular member 11. Thus, as illustrated in FIG. 11A where severed polyps 31 and polyps 31A and 31B have been sequentially severed and retained, the polyps 31, 31A and 31B would reside between the legs 52 in a secure position at the distal end 51 of the clip 50.

Use of this embodiment enables the physician to associate the polyps with the position from which it was severed. Thus, for example, only a portion of the plurality of the captured polyps are found to be cancerous, this ability to determine the location can be used to determine what segments of the lumen 23 need to be surgically removed. Use of this embodiment also eliminates the waste of time involved in removing from the patient's lumen 23 the tubular member 11 and generally an associate endoscope through which the tubular member is extended to retrieve a severed polyp after each severing and capturing operation.

FIG. 12 depicts still another apparatus 60 according to this invention that comprises a radially flexible, axial stiff elongated catheter or tubular member 61 having a distal end 62 from which a severing device 63 and a capturing device 64 extend and retract. The severing device 63 and the capturing device 64 connect at their proximal ends to a cable 65 and a hollow cable or hypotube 66, respectively, that extend proximal through lumens 67 and 68 (FIG. 13) in the tubular member 61 to a two part handle 69. The severing device 63 comprises an expansible snare 70, the capturing device 64, and a forceps-needle combination 71 that extends through a sheath 72 and that includes a hollow needle 71A that conveys fluid into a polyp.

Referring now to FIGS. 12, 14 and 15, a physician controls the operation of the forceps-needle combination 71 and the snare 70 from the handle 69 at a proximal end of the apparatus. A first portion 73 of the handle 69 (FIG. 14) supports a slider 74 that attaches to the cable 65. Distal displacement of the slider 74 enables the physician to extend the snare 70 from the distal end 62 as depicted in FIG. 12; proximal displacement of the slider 74 retracts the snare 70 as depicted in FIG. 17.

The handle 69 also includes an electrical plug 83 that suitably connects with the cable 65 to provide mono-polar cauterization of a base of a polyp severed by the snare 70. Alternatively, the electrical plug 83 can be eliminated in cases not needing cauterization or hypotube 66 can suitably connect plug 84 with the forceps needle combination 71 to enable bi-polar cauterization.

A second portion 75 (FIG. 15) of the handle 69 includes a slider 76 disposed in a slidable housing 77 supported in an outer housing 78 as depicted in cross-section in FIG. 15. The sheath 72 connects with the slider 76. Displacement of the slider 76, connected to sheath 72, relative to the slidable housing 77, connected to hypotube 66 and thus connected to capturing device 64, displaces the sheath 72 relative to the forceps-needle combination 71, thus enabling the extension, as depicted in FIG. 12, and retraction as depicted in FIG. 16. The hypotube 66 secures to a proximal end 80 of the slidable housing 77 so that displacement of the slidable housing 77 and the slider 76 together displaces the forceps needle combination 71 and the sheath 72 relative to the distal end 62 of the tubular member 61 (FIGS. 12 and 17). A proximal end 81 of the hypotube 66 in this embodiment includes an injection hub 82.

In operating the apparatus 60, the physician preferably positions the tubular member 61 to extend from the working channel of an endoscopic device 100 previously inserted in a patient. The physician manipulates the slider 74 and the slidable housing 77 and the slider 76 to extend the snare 70 and the forceps-needle combination 71 over a polyp 85, as depicted in FIG. 12. If the polyp 85 is a relatively small, flat polyp of a type that is usually difficult to sever and/or retrieve by prior art apparatus, the physician positions the snare 70 to encompass a base 86 of the polyp 85 and pierces the polyp 85 with the needle 71A between the base 86 and a free end 87 of the polyp 85 to inject a suitable fluid (e.g., a saline solution or sclerotherapy agents) into the polyp 85 from the injection hub 82 to expand and swell the polyp 85. The physician then closes forceps legs 71B of the forceps needle combination 71 to capture the now swollen polyp 85 by distal displacement of the sheath 72 relative to the forceps legs 71B (FIG. 16). Retraction of the snare 70 severs the polyp 85 so that the forceps-needle combination 71 retains the severed portion including the free end 87. Retracting the slidable housing 77 and distal displacing the slider 76, as shown in FIG. 17, moves the forceps-needle combination 71 into close proximity of the distal end 62.

FIGS. 18 and 19 depict distal portions of the apparatus 60 with alternative capturing devices 64A and 64B, respectively. The embodiment of FIG. 18 includes only a forceps device 89 with extending legs 90. Those skilled in the art will understand that in this case the hypotube 66 can be solid and that the sheath 22 can, alternatively, be omitted so that the legs 90 expand and contract upon extension and retraction relative to the distal end 62 of the tubular member 61. Additionally, the hypotube 66 can be connected to a slider suitably mounted in a handle (not shown) similarly to the slider 74 of FIG. 12 with the slidable housing 77 of FIG. 12 also omitted.

The capturing device 64 of the embodiment of FIG. 19 includes only a needle 91 without any forceps device. The needle 91 operates substantially the same as the needle 71A of the embodiment of FIG. 12. That is, it connects with a proximal slidable member (not shown) to extend and retract the needle 91 and includes a means for enabling a fluid to be injected through the needle 91. The needle 91 further includes one or more barbs 92 or other similar surface features formed thereon proximate its distal end. The barbs 92 tend to retard withdrawal of the needle 91 from the polyp 85. Consequently, the polyp 85 tends to remain on the needle 91.

Thus, after severing the polyp 85 by the snare 70, the severed portion polyp 85 including the free end 87 can be removed by withdrawal of the elongated tubular member 61. This embodiment also enables the collection of additional polyps by successively extending and positioning the snare 70 and needle 91 and then retracting the snare 70, as discussed above. That is to collect an additional selected polyp, such as the polyp 85 after collecting polyps 85B and 85A, respectively, the user positions the distal end of the device proximate the polyp 85 and extends the snare 70 to encompass the polyp and the needle 91 to pierce the polyp. Upon piercing the selected polyp 85, previously severed polyps retained on the needle 91 are urged proximally along the needle 91. The user can then inject the polyp 85 with a suitable solution, if desired, prior to severing the polyp 85 by retracting the snare 70. Once severed, the polyp 85 would be retained on the needle 91 as described above. Thus, as illustrated in FIG. 19A, a plurality of polyps severed and retained in the sequential order of the polyps 85B, 85A, 85 are retained proximate the distal end of the needle 91.

In summary, there have been described various embodiments of devices for severing and capturing polyps without prior art surgical intervention. Specifically, these devices include a catheter or like elongated tubular member having

one or more lumens therein adapted for extending through the working channel of an endoscopic device having a viewing channel. Severing and capturing devices connect with control apparatus at the proximal end of the catheter to enable extension and retraction of the severing and capturing device relative to the distal end of the catheter. This structure enables a physician to selectively grasp a polyp, sever a portion of the polyp from its base and withdraw the polyp from the patient. The severing device typically includes a snare. The capturing device may comprise a closed end clip, legs arranged in a forceps-like configuration, a barbed needle, or combination thereof. A needle can also allow a physician to inject fluid into a polyp thereby to enlarge the polyp and facilitate its severing and its removal.

Those skilled in the art will further appreciate that the described devices can be relatively easily constructed according to known methods and relatively easily used by physicians familiar with prior art devices. However, this invention provides physicians with devices that are more versatile in dealing with polyps and that are relatively easily used while also providing greater surety in retention of the portions of polyps that are severed as compared with the prior art devices. This invention has been disclosed in terms of certain embodiments. It will be apparent that many modifications can be made to the disclosed apparatus without departing from the invention. Therefore, it is the intent of the appended claims to cover all such variations and modifications as come within the true spirit and scope of this invention.

What is claimed as new and desired to be secured by Letters Patent of the United States is:

1. An endoscopic instrument for severing and capturing a polyp from a patient, the instrument comprising:

a catheter having a distal end and a proximal end;

a first cable extending between said distal end and said proximal end of said catheter;

a snare for severing the polyp from the patient, said snare being coupled to a distal end of said first cable and being at least partially extensible from and at least partially retractable into said distal end of said catheter;

second cable extending between said distal end and said proximal end of said catheter;

a self-expansible forceps for holding the severed polyp, said forceps being coupled to a distal end of said second cable and being at least partially extensible from and at least partially retractable into said distal end of said catheter, said snare and said forceps configured so that said forceps is capable of holding a portion of the polyp to be severed and removed while said snare severs the polyp;

a needle for piercing the polyp, said needle coupled to said distal end of said second cable; and

a control device coupled to said proximal end of said catheter for extending and retracting said snare and for extending and retracting said forceps and said needle relative to said distal end of said catheter.

2. The instrument of claim 1, wherein said needle is hollow and said second cable is hollow.

3. The instrument of claim 1, wherein said control device includes a first slider coupled to a proximal end of said first cable and slidably coupled to said control device and a second slider coupled to a proximal end of said second cable and slidably coupled to said control device.

4. An endoscopic instrument for severing and capturing a polyp from a patient, the instrument comprising:

an elongate catheter having a distal end and a proximal end;

a first flexible member extending through said catheter and having a distal end and a proximal end;

a severing device coupled to said distal end of said first flexible member and being at least partially extensible from said distal end of said catheter;

a second flexible member extending through said catheter and having a distal end and a proximal end;

a self-expansible capturing device coupled to said distal end of said second flexible member and being at least partially extensible from said distal end of said catheter, said severing device and said capturing device configured so that said capturing device is capable of retaining the portion of the polyp to be severed and removed while said severing device severs the polyp;

a needle coupled to said distal end of said second flexible member; and

a control device coupled to said proximal end of said catheter, said proximal end of said first flexible member and said proximal end of said second flexible member, said control device capable of moving said severing device relative to said catheter and said capturing device relative to said catheter.

5. The instrument of claim 4, wherein said needle is hollow and said flexible member, which is coupled to said needle, is hollow.

6. The instrument of claim 4, wherein said severing device includes a snare.

7. The instrument of claim 4, wherein said capturing device includes a forceps.

8. The instrument of claim 4, wherein said control device includes a first slider coupled to said proximal end of said first flexible member and slidably coupled to said control device and a second slider coupled to said proximal end of said second flexible member and slidably coupled to said control device.

9. The instrument of claim 4, wherein an elongate sheath extends between said distal end and said proximal end of said catheter, said elongate sheath having a distal end and a proximal end, and said control device being coupled to said proximal end of said sheath and capable of moving said sheath relative to said catheter.

10. The instrument of claim 9, wherein said control device includes a first slider coupled to said proximal end of said first flexible member and slidably coupled to said control device, a second slider coupled to said proximal end of said second flexible member and slidably coupled to said control device, and a third slider coupled to said proximal end of said sheath and slidably coupled to said control device.

* * * * *

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(12) **United States Patent**
Chu et al.

(10) **Patent No.: US 6,171,315 B1**
(45) **Date of Patent: Jan. 9, 2001**

(54) **APPARATUS FOR SEVERING AND CAPTURING POLYPS**

(75) Inventors: **Michael S. H. Chu**, Brookline; **Yem Chin**, Burlington, both of MA (US)

(73) Assignee: **Boston Scientific Corporation**, Natick, MA (US)

(*) Notice: Under 35 U.S.C. 154(b), the term of this patent shall be extended for 0 days.

(21) Appl. No.: **09/457,700**

(22) Filed: **Dec. 9, 1999**

Related U.S. Application Data

(62) Division of application No. 09/146,105, filed on Sep. 3, 1998, now Pat. No. 6,010,512, which is a division of application No. 08/421,409, filed on Apr. 13, 1995, now Pat. No. 5,846,248.

(51) **Int. Cl.**[7] **A61B 17/32**
(52) **U.S. Cl.** **606/113**
(58) **Field of Search** 606/113, 194, 606/46, 110, 47

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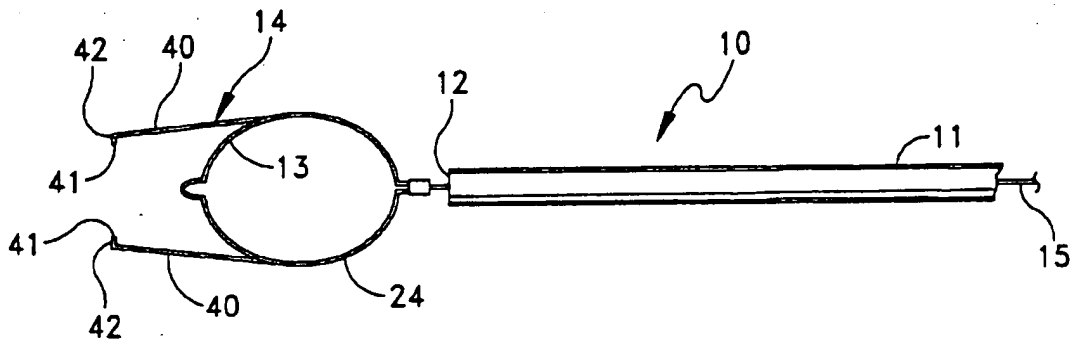
Primary Examiner—Michael H. Thaler
(74) *Attorney, Agent, or Firm*—Finnegan, Henderson, Farabow, Garrett & Dunner LLP

(57) **ABSTRACT**

A method and apparatus for managing polyps by which an elongated tubular member generally positionable within the working channel of an endoscopic device. The tubular member carries a selectively extendable severing device and capturing device at its distal end. Control apparatus at the proximal end of the tubular member enables a physician to extend and retract the severing and capturing devices. The physician retracts the capturing device to grasp the portion of the polyp to be severed and retracts the severing device to sever the polyp. The capturing device retains the severed portion of the polyp for removal with the tubular member. In one embodiment the capturing device includes an injection needle.

19 Claims, 7 Drawing Sheets



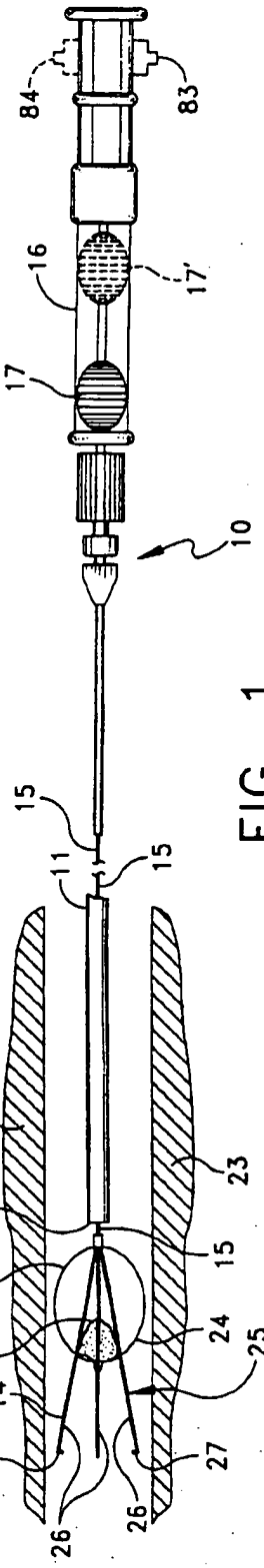


FIG. 1

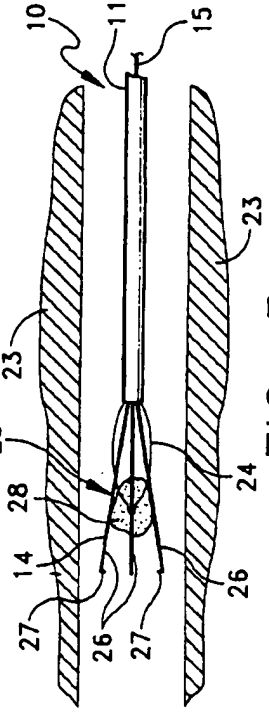


FIG. 3

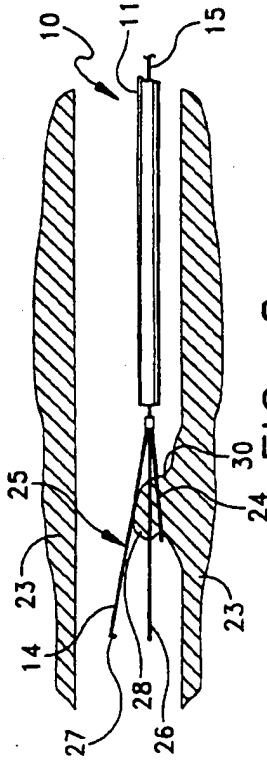


FIG. 2

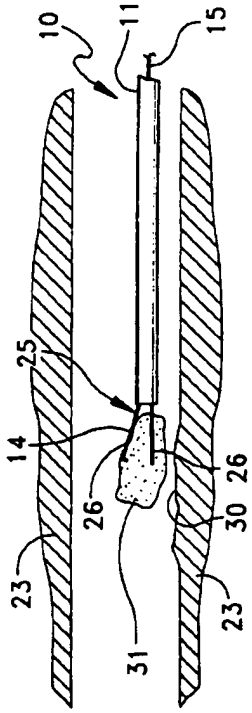


FIG. 4

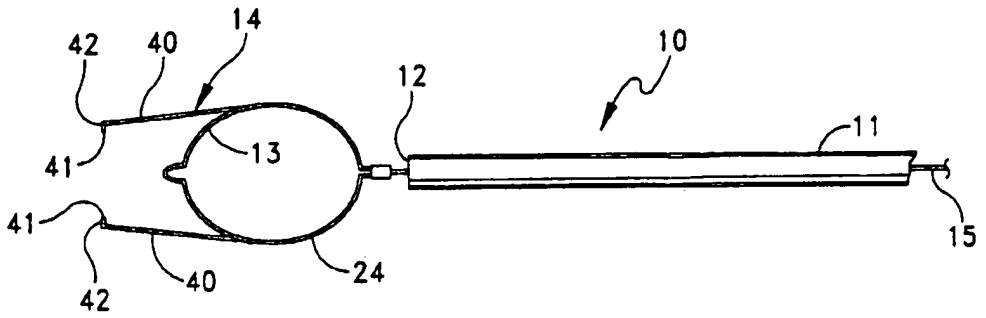


FIG. 5

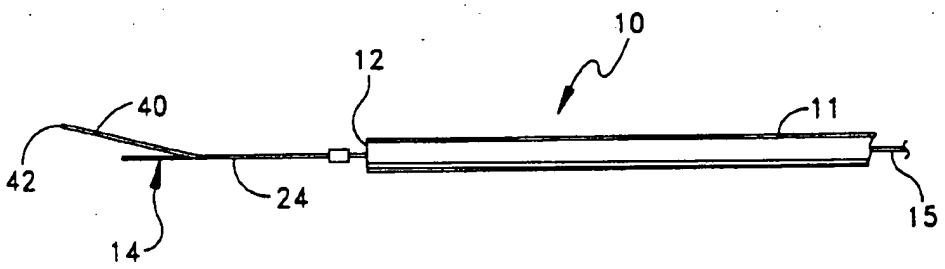


FIG. 6

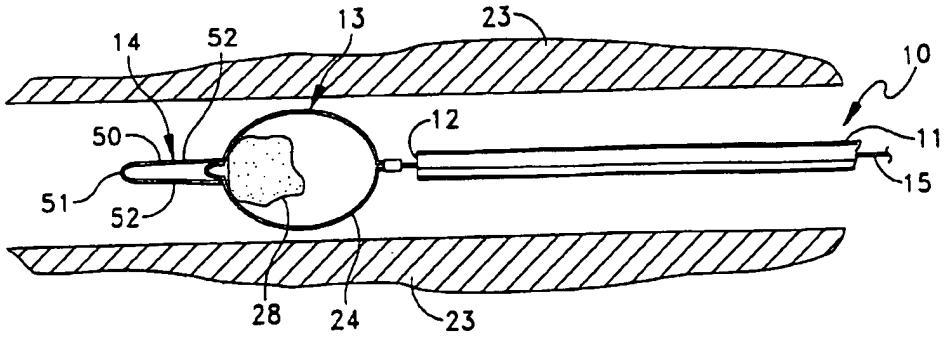


FIG. 7

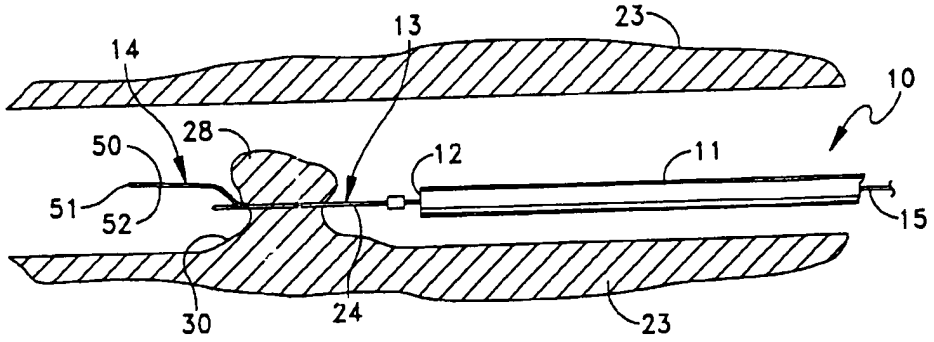


FIG. 8

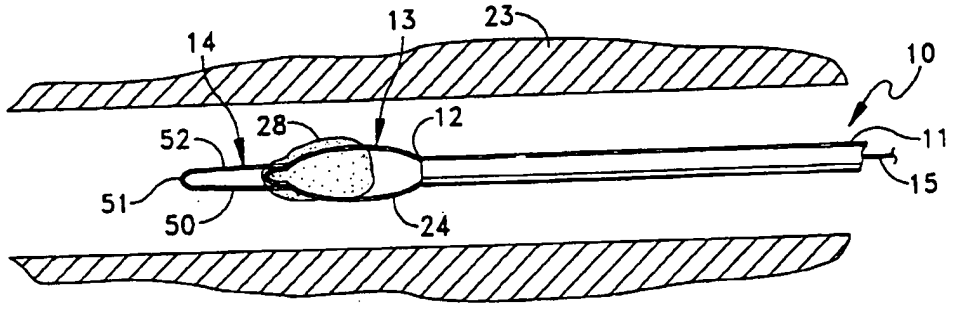


FIG. 9

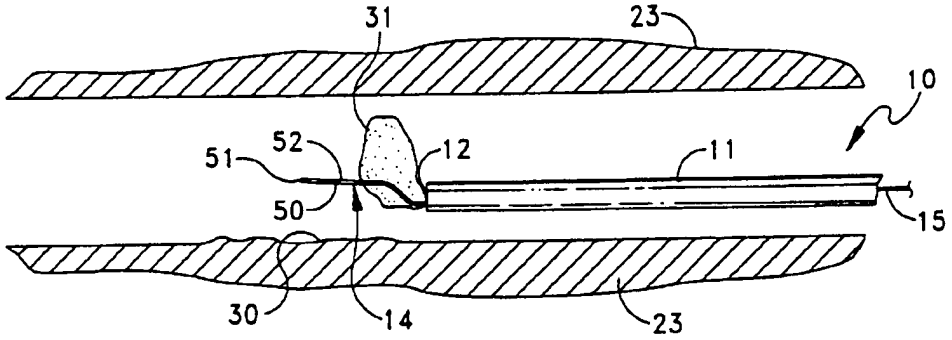


FIG. 10

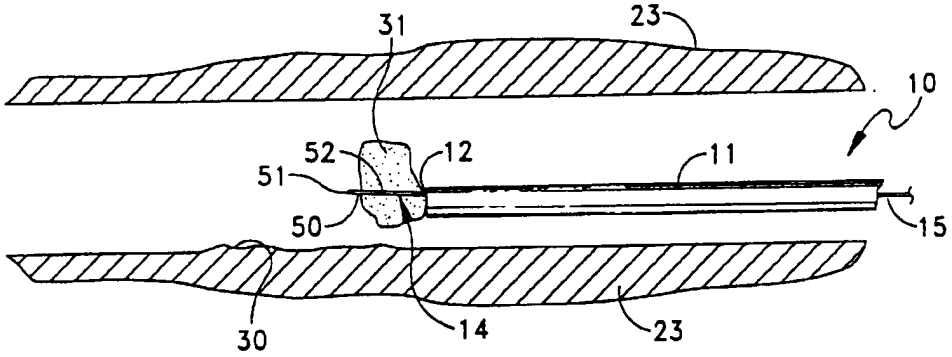


FIG. 11

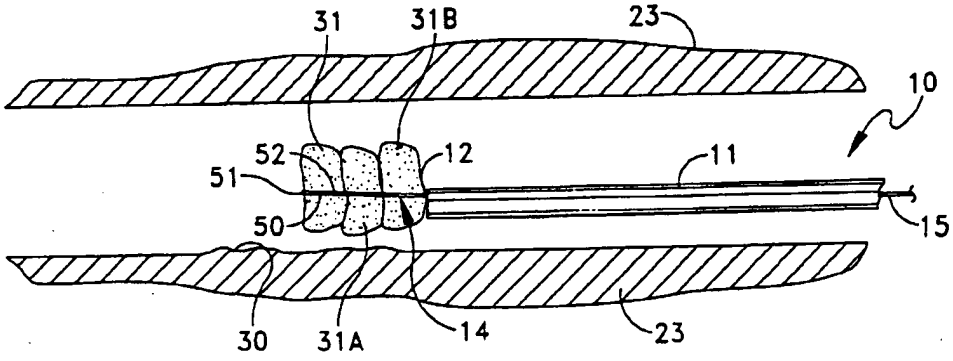


FIG. 11A

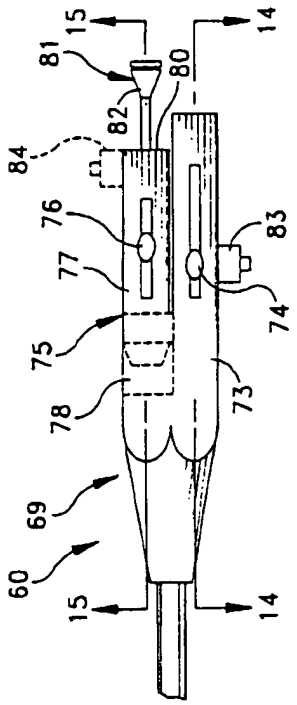


FIG. 12

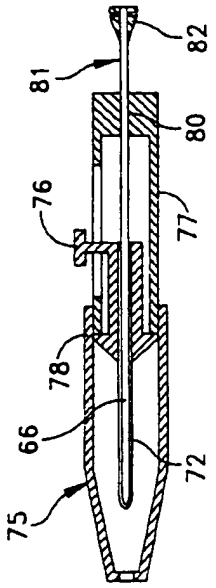


FIG. 15

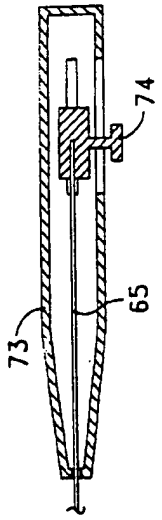
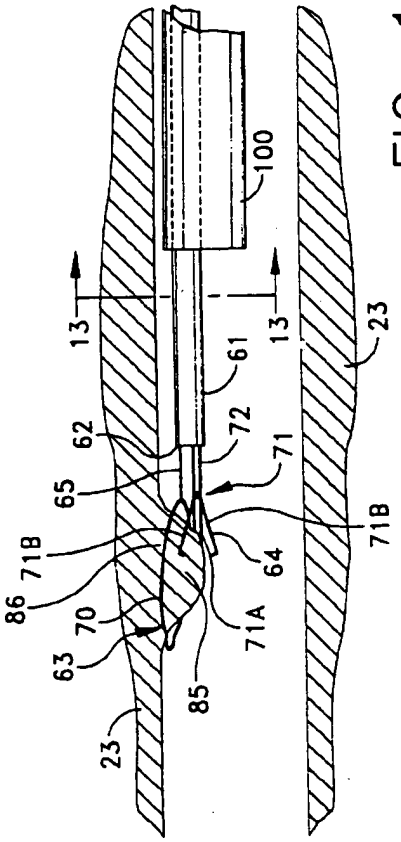


FIG. 14



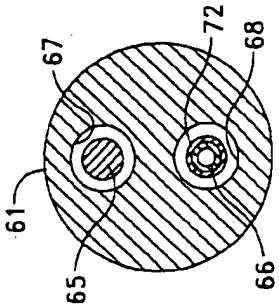


FIG. 13

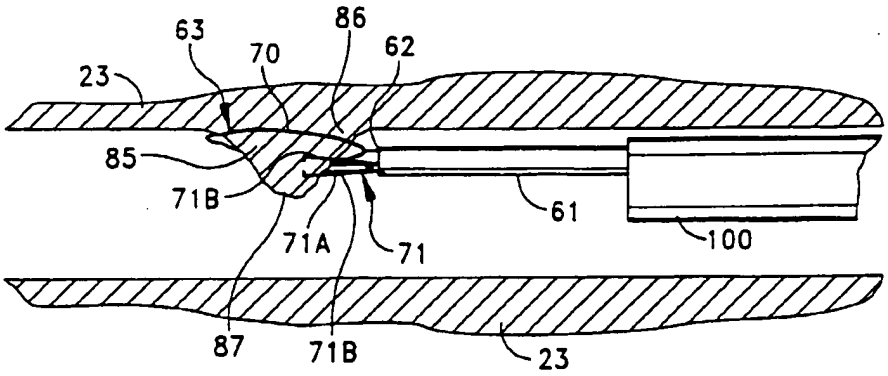


FIG. 16

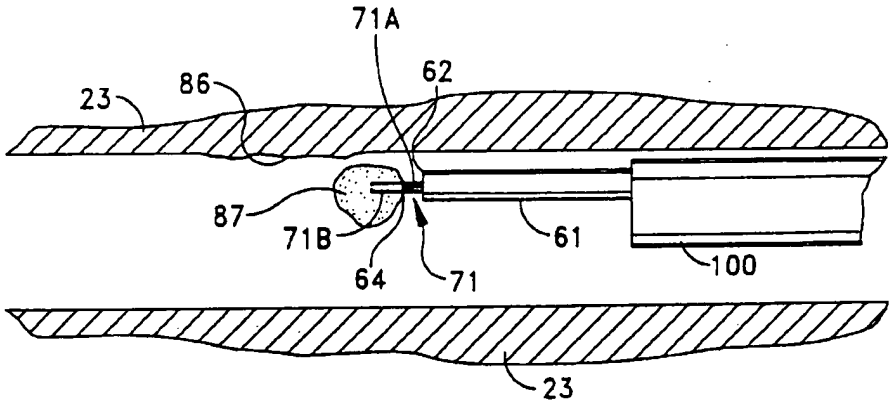


FIG. 17

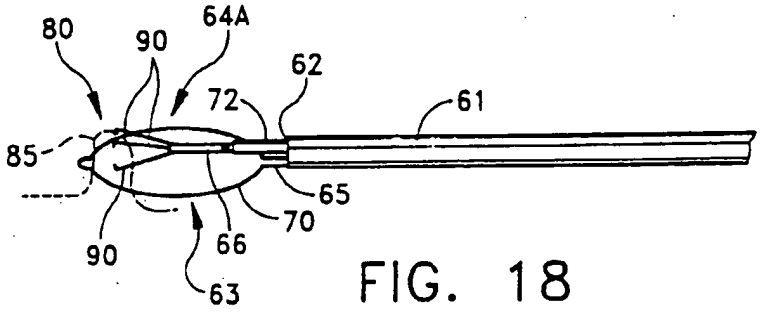


FIG. 18

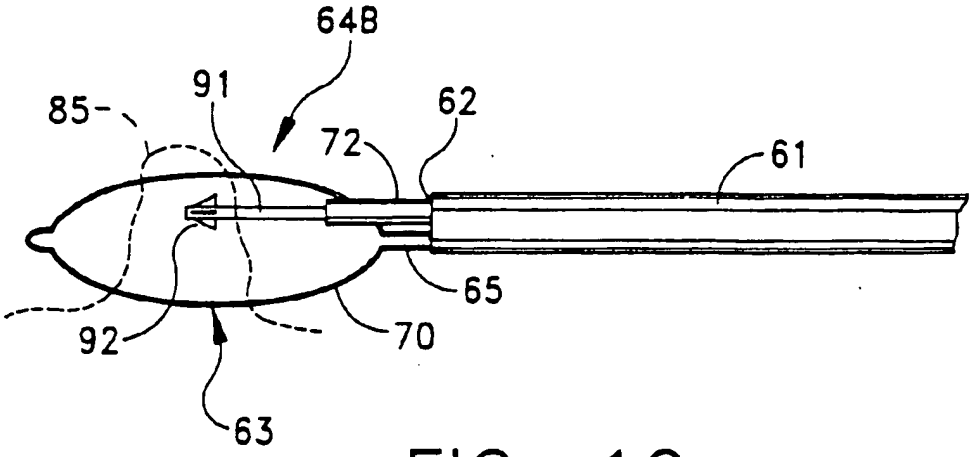


FIG. 19

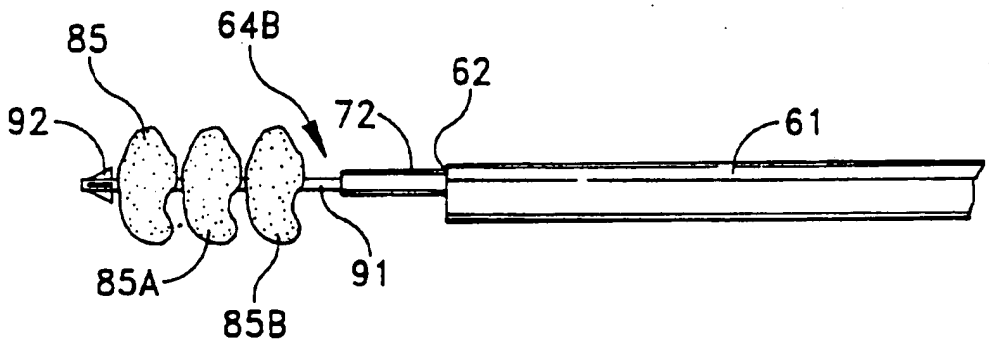


FIG. 19A

APPARATUS FOR SEVERING AND CAPTURING POLYPS

This is a divisional of application Ser. No. 09/146,105, filed Sep. 3, 1998, now U.S. Pat. No. 6,010,512 which is a divisional application of Ser. No. 08/421,409 filed Apr. 13, 1995, now U.S. Pat. No. 5,846,248 which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to surgical apparatus and methods for polyp management and more particularly to such apparatus and methods for severing and capturing polyps.

2. Description of Related Art

The treatment of polyps and other similar growths in a patient has improved greatly within the last several decades. Polyps are generally collected for histopathological evaluation to determine if they are cancerous. Initially the primary method of treating polyps was major surgery. Now polypectomy procedures are based upon the insertion of a surgical catheter through the working channel of an endoscope. Polypectomy procedures have essentially replaced surgical procedures except when polypectomy procedures are deemed unsuitable, such as when the polyp or polyps to be removed are relatively planar in nature. As used in this application, an endoscope includes a endoscopic or other similar device that is inserted into a patient and that includes a working channel for receiving a surgical catheter or the like and a viewing channel for viewing the interior of a vessel.

The following United States Letters Patent disclose surgical apparatus for polyp management procedures:

U.S. Pat. No. 5,122,147 (1992) Sewell, Jr.

U.S. Pat. No. 4,326,530 (1982) Fleury, Jr.

Sewell, Jr. discloses several embodiments of a polyp marking device and method of using them. FIG. **4** illustrates three generally concentric loops extending from the distal end of the housing. Spacing members contact each loop thereby to position the loops along radially inner, outer and underneath paths. The inner loop **20** has one end fixed to the housing and rachets onto a polyp proximate its base by retraction of a second end extending distally through the housing. The outer loop **23** retracts to grasp the polyp proximate its free end. An intermediate cutting loop has one end fixed in the housing and severs the polyp by retraction of a second end extending through the housing. The inner loop **20** remains attached to the base of the severed polyp.

In another embodiment disclosed by Sewell, Jr. retraction of a cutting loop **21** severs an inner loop **20** from a housing. After such retraction, a forceps device is inserted through the distal end of the housing.- Manipulation of the forceps device enables a physician to capture the severed portion of the polyp. Other embodiments disclosed by Sewell, Jr. disclose clamping devices or jaws having one or more cutting edges for severing a polyp whereby the jaws close to return the severed portion of the polyp. Sewell, Jr. avoids the use of an electric current for cauterizing the severed base by applying a hemostatic agent to the base of the polyp from the inner loop.

Fleury, Jr. discloses a surgical instrument for removing cellular tissue from body cavities. The instrument includes a proximal handle and a distally extending tubular member. A cable passes through the tubular member and includes a self-expanding loop or snare at its distal end. Extension and retraction of the cable enables the loop to enlarge and

encompass a polyp and then to contract and sever the polyp. The loop conducts rf electrical current to cauterize the stump of the severed polyp. However, the catheter of Fleury, Jr. does not provide apparatus associated with the instrument itself for capturing the severed portion of the polyp. Rather Fleury, Jr. suggests that other suitable means such as suction associated with a colonscope equipment (i.e., an endoscopic device) captures the severed portion.

Another type of know surgical catheter for performing polypectomy procedures includes a loop or snare disposed at the distal end of the catheter. A basket or net connects to the loop along its defined arc. In use the basket overlies the portion of a polyp to be severed by the loop. Thus, upon severing of the polyp the basket captures the severed portion.

The advantages of such prior art polypectomy procedures in contrast to major surgery are numerous. The advantages generally include reductions in the time and trauma of the operation itself, the time of recovery of the patient, the risk of infection and other problems associated with major surgery. Thus, a surgical catheter device of the prior art generally includes a tubular member extensible through the working channel of an endoscopic device with a cutting loop positioned at the distal end of the tubular member and may include a mechanism for cauterizing the base of a severed polyp.

However, prior art polypectomy devices sometimes are unsuitable for treating certain polyps and are cumbersome and often extend the duration of a procedure unnecessarily.

Some embodiments disclosed by Sewell, Jr., for example, require the use of a separate forceps instrument used in conjunction with the disclosed instrument to retrieve the severed polyp. Generally, Sewell, Jr. discloses a device which requires multiple control wires, three wires in the case of the embodiment of FIG. 4. Furthermore, Sewell, Jr. leaves the inner loop within the body of the patient so that it must be retrieved or otherwise passed from the patient's body.

The device disclosed by Fleury, Jr. also has limited usefulness because it does not include any apparatus for grasping the severed portion. Although some endoscopic devices use suction to extract tissue, the suction, at acceptable levels, is frequently insufficient to hold a severed polyp at the end of the device. Using suction also requires positioning the distal end of the endoscope proximate the polyp. This is not always a simple task. It frequently requires a high degree of skill and dexterity. Should the polyp not be held, it is often difficult to retrieve the severed polyp. Using a forceps device to retrieve such severed portion usually requires the removal of the surgical catheter from the working channel of the endoscope device and insertion of the forceps device. The snare and basket arrangements offer the possibility of retrieving several polyps without removing the apparatus from a patient. However, the weight of the basket depending from the snare tends to deflect the snare and the distal end of the surgical instrument. Consequently it can be difficult to maneuver the snare over a selected polyp. The loops of the basket overlying the snare also can impede snare closure and severance of a selected polyp. Moreover, the movement of the basket loops along the snare tends to dull the snare and makes the severing more difficult. The baskets, being metallic, can contact the snare and bypass current used for cauterizing the severed stump of the polyp. Also, in the case where multiple polyps are collected there is no means to adequately associate the particular polyps collected with the location from which such polyps were taken.

The prior art taken collectively, thus fails to provide an easily used and simply constructed surgical apparatus for

effectively and reliably severing and capturing polyps of diverse shapes and sizes. There is no suggestion of a method and apparatus for efficiently and effectively capturing a polyp or severing and capturing successive polyps in a reliable manner and, additionally, being able to associate the position from which such polyps were taken with particular polyps. Further, the prior art devices which require repeated removal and insertion to take a plurality of polyps generally also require repeated removal and insertion of the endoscope, because polyps frequently are larger than the working channel of such endoscopes. Thus, the repeated insertion and removal increases the time for such polypectomy procedures and associated trauma to the patient.

SUMMARY

Therefore, it is an object of the present invention to provide a surgical apparatus for effectively and reliably severing and capturing a polyp.

Another object of this invention is to provide a surgical apparatus that is simple to manufacture and use and that efficiently and effectively captures and severs a polyp.

Still another object of this invention is to provide a method for managing polyps that enables a physician to efficiently and effectively remove polyps from a patient.

Yet another object of this invention is to provide a surgical apparatus having a holding device and a severing device positioned at a distal end of the apparatus that are independent of each other.

Yet still another object of this invention is to provide a surgical apparatus having a control mechanism for concurrent extension and retraction of a holding device and a severing device positioned at a distal end of the apparatus.

Still yet another object of this invention is to provide a method for severing and capturing a polyp that includes the step of positively holding the polyp prior to severing such that the severed portion of the polyp is captured.

Yet a further object of this invention is to provide a method and apparatus for enlarging a polyp to promote severing and for capturing a polyp.

Still yet a further object of this invention is to provide a method and apparatus for successive severing and capturing of polyps within a patient prior to removal of the apparatus.

A further object of this invention is to provide a method and apparatus for retaining severed and captured polyps in an order corresponding to the order of such severing and capturing.

According to one aspect of this invention apparatus for severing and retaining a polyp includes an axially extending catheter with a distal end that can be positioned proximate a polyp. A self-expansible severing and capturing device is extensible from the distal end in an expanded form and is retractable into the catheter in a compacted form. Actuation of a control device at a proximal end of the catheter externally of the patient enables extension and retraction of the severing and capturing device relative to the distal end of the catheter thereby to enable polyp removal.

According to another aspect of this invention a surgical instrument, adapted for use in the working channel of an endoscopic device and for capturing and severing a portion of a polyp, includes an elongated tubular, member extending proximally from a distal end and a snare carried by the tubular member for encompassing and severing a polyp. Selective extension of a holding device carried by the tubular member independently of the snare holds the polyp proximate its free end so that upon severing of the polyp the holding device retains the severed portion of the polyp.

According to yet another aspect of this invention a surgical instrument for severing and capturing a polyp includes an elongated tubular member proximally extending from a distal end and adapted to extend through the working channel of an endoscopic device with a viewing channel. The tubular member supports a snare for extension in an enlarged condition and retraction in a compact condition relative to the distal end. Control apparatus enables a physician to selectively extend and retract the snare. A capturing device connects with the control apparatus for extension and retraction with the snare so that upon retraction the capturing device grasps and retains a portion of the polyp severed by the snare.

According to a further aspect of this invention a method for managing polyps in a patient includes locating a catheter proximate a selected polyp. Extension of a self-expansive severing device from the catheter encompasses the polyp proximate its base. Extension of a holding device from the distal end of the catheter upon maneuvering engages the polyp proximate a free end thereof. Retracting the severing device into the catheter severs the polyp proximate the polyp's base; the holding device retains the severed portion that includes the free end.

According to yet a further aspect of this invention a method for managing polyps in a patient includes locating a catheter proximate a select polyp. Extension and orientation of a severing and holding device from the catheter includes encompassing the polyp with a severing portion of the device and a holding portion of the device engaging the polyp proximate a free end thereof. Retraction of the severing and holding device severs the polyp with the holding portion of the device retaining a separate portion including the free end of the selected polyp.

BRIEF DESCRIPTION OF THE DRAWINGS

The appended claims particularly point out and distinctly claim the subject matter of this invention. The various objects, advantages and novel features of this invention will be more fully apparent from a reading of the following detailed description in conjunction with the accompanying drawings in which like reference numerals refer to like parts, and in which:

FIG. **1** is a plan view of a surgical instrument constructed in accordance with this invention having a severing and holding device at a distal end portion for location within a patient proximate a polyp;

FIG. **2** is a enlarged side elevation of a distal end portion of FIG. **1**;

FIG. **3** is a enlarged plan view of the distal end portion of FIG. **1** with the severing and holding device in partially retracted position;

FIG. **4** is a enlarged plan view of the distal end portion of FIG. **1** with the severing and holding device in a retracted position with the polyp severed at is base and the severed portion retained by the holding device;

FIG. **5** is an enlarged plan view of the distal end portion of another surgical instrument in accordance with this invention;

FIG. **6** is an enlarged side elevation of the distal end portion of the embodiment of FIG. **5**;

FIG. **7** is an enlarged plan view similar to FIG. **5** of the distal end portion of another surgical instrument in accordance with this invention;

FIG. **8** is a side elevation of the distal end portion of FIG. **7**;

FIG. 9 is a plan view of the embodiment of FIG. 7 with the severing and holding device in a partially retracted position;

FIG. 10 is a plan view of the embodiment of FIG. 7 with a severing portion of the severing and holding device retracted into the tubular member;

FIG. 11 is a plan view of the embodiment of FIG. 7 with the distal portion of a holding portion of the severing and holding device retracted proximate the distal end of the tubular member;

FIG. 11A is a view of the embodiment of FIG. 7 similar to FIG. 11 with the distal portion of the holding portion having a plurality of severed polyps retained therein;

FIG. 12 is a side elevation of a yet another surgical instrument constructed in accordance with this invention with a severing device and a holding device in an extended position relative to a tubular member;

FIG. 13 is a cross-section of the tubular member of FIG. 12 taken along the line 13—13;

FIG. 14 is a cross-section of the handle portion of FIG. 12 taken along the line 14—14;

FIG. 15 is a cross-section of the handle portion of FIG. 12 taken along the line 15—15;

FIG. 16 is a side elevation of the distal portion of FIG. 12 with the holding device and the severing device partially retracted into the tubular member;

FIG. 17 is similar to FIG. 16 with the severing device retracted and the holding device retracted proximate the distal end of the tubular member;

FIG. 18 is a perspective view of a distal portion of yet still another surgical instrument in accordance with this invention;

FIG. 19 is a perspective view of a distal portion of a further surgical instrument in accordance with this invention; and

FIG. 19A is the view of FIG. 19 with a plurality of severed polyps retained on the retaining portion of the device and with the severing portion retracted.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

As depicted in FIG. 1, apparatus 10 for managing polyps according to this invention includes a radially flexible, axial stiff elongated catheter or tubular member 11 extending proximally from a distal end 12 with a severing device 13 and a capturing device 14 extensible from and retractable relative to the distal end 12. The severing device 13 and the capturing device 14 connect at their proximal ends to a cable 15 that extends through the catheter 11 to a handle 16. The cable 15 in this embodiment connects to a slide member 17 suitably supported in the handle 16, although alternatively the cable can be fixed to the handle 16 with the slide member 17 connecting to the tubular member 11. Those skilled in the art will appreciate that displacement of the slide member 17 enables a user to selectively control the distal extension and proximal retraction of the severing device and the capturing device relative to the distal end 12.

FIGS. 1 through 4 illustrate the use of the present invention which is preferably used with a known endoscopic device having a working channel and a viewing channel. The severing device 13 in this embodiment is formed as a snare 24, and the capturing device 14 comprises forceps 25 with distally extending legs 26 secured to the snare extending from the distal end of the cable 15. Each of the legs 26 includes an inwardly extending portion 27 at its free or distal end.

In use, a physician inserts the distal end 12 through the working channel of an endoscope and uses the viewing channel to position the distal end 12 proximate a polyp 28. Once the severing and capturing devices 13 and 14 are extended relative to the distal end 12, the physician maneuvers the severing device 13 to encompass the polyp 28 proximate its base 30. The proper maneuvering of the severing device also positions the capturing device 14 as illustrated in FIGS. 1 and 2. The physician then retracts the cable 15 relative to the distal end 12 by moving the slide member 17 (FIG. 1) from its distal position toward the position 17' to displace the severing and capturing device 13 and 14 into the tubular member 11. As depicted in FIG. 3, retraction of the severing device 13 and the capturing device 14 causes the severing device 13 to close and sever a portion 31 of the polyp 28 and concurrently to urge the severed portion 31 into engagement between the legs 26. Thus, after the severing of the polyp 28 the severed portion 31 is retained by the capturing device 14 so that it can be removed from the patient as the tubular member 11 is withdrawn.

FIGS. 5 and 6 depict an alternative embodiment including a severing device 13 and a capturing device 14. In this case the capturing device 14 comprises two leg members 40 extending from opposed central portions of the snare 24 to define a plane intersecting the plane of the snare 24. Retraction of the severing device 13 and the capturing device 14, once positioned so that the severing device 13 encompasses a polyp 28 with the capturing device 14 disposed proximate the free end of the polyp 28, urges the leg members 40 toward each other so that the portion 31 of the polyp 27 to be severed from the base 30 is grasped or gripped by the leg members 40 enabling retention and removal of the polyp from the patient. Each of the leg members 40 may also include a radially inwardly extending projection 41 proximate free ends 42 to capture the severed portion 31 in a positive fashion.

FIGS. 7 through 11 depict another embodiment of this invention that includes a severing device 13 and a capturing device 14 that are formed as a snare 24 and a collar or clip 50, respectively. The clip 50 has a closed distal end 51 with legs 52 extending proximally therefrom. The legs 52 attach to opposed central portions of the snare 24 so that the clip lies outside the plane defined by the snare 24. In using this embodiment, a physician positions the snare 24 to encompass a polyp 28 proximate its base and the clip 50 opposite the base 30 of the polyp 28. Retraction of the snare 24 into the tubular member 11, as depicted in FIGS. 9 and 10, severs the polyp 28 and urges the severed portion 31 into the clip 51. Further retraction, as depicted in FIG. 11 urges the severed portion 31 into a secure position against the distal end of the clip 51. It will be appreciated by those skilled in the art that providing a collar or clip of sufficient distal extension for receiving a plurality of polyps will enable the removal of such polyps prior to removal of the apparatus 10 from the patient's lumen 23.

The embodiment of FIG. 7 thus enables the grasping and retention of a plurality of polyps. The plurality of retained polyps will be arranged sequentially with the distal most polyp corresponding to the first sample sequentially with the proximal most polyp being the last polyp captured. Thus, the polyps will be stacked in the clip in the order of severing. Specifically each polyp is urged distally in the clip 50, as the cable 15 is retracted to bring the distal end 51 of the clip 50 proximate the distal end 12 of the tubular member 11. Thus, as illustrated in FIG. 11A where severed polyps 31 and polyps 31A and 31B have been sequentially severed and retained, the polyps 31, 31A and 31B would reside between the legs 52 in a secure position at the distal end 51 of the clip 50.

Use of this embodiment enables the physician to associate the polyps with the position from which it was severed. Thus, for example, only a portion of the plurality of the captured polyps are found to be cancerous, this ability to determine the location can be used to determine what segments of the lumen **23** need to be surgically removed. Use of this embodiment also eliminates the waste of time involved in removing from the patient's lumen **23** the tubular member **11** and generally an associate endoscope through which the tubular member is extended to retrieve a severed polyp after each severing and capturing operation.

FIG. **12** depicts still another apparatus **60** according to this invention that comprises a radially flexible, axial stiff elongated catheter or tubular member **61** having a distal end **62** from which a severing device **63** and a capturing device **64** extend and retract. The severing device **63** and the capturing device **64** connect at their proximal ends to a cable **65** and a hollow cable or hypotube **66**, respectively, that extend proximal through lumens **67** and **68** (FIG. **13**) in the tubular member **61** to a two part handle **69**. The severing device **64** comprises an expansible snare **70**, the capturing device **63**, a forceps-needle combination **71** that extends through a sheath **72** and that includes a hollow needle **71A** that conveys fluid into a polyp.

Referring now to FIGS. **12**, **14** and **15**, a physician controls the operation of the forceps-needle combination **71** and the snare **70** from the handle **69** at a proximal end of the apparatus. A first portion **73** of the handle **69** (FIG. **14**) supports a slider **74** that attaches to the cable **65**. Distal displacement of the slider **74** enables the physician to extend the snare **70** from the distal end **62** as depicted in FIG. **12**; proximal displacement of the slider **74** retracts the snare **70** as depicted in FIG. **17**.

The handle **69** also includes an electrical plug **83** that suitably connects with the cable **65** to provide mono-polar cauterization of a base of a polyp severed by the snare **70**. Alternatively, the electrical plug **83** can be eliminated in cases not needing cauterization or hypotube **66** can suitably connect plug **84** with the forceps needle combination **71** to enable bi-polar cauterization.

A second portion **75** (FIG. **15**) of the handle **69** includes a slider **76** disposed in a slidable housing **77** supported in an outer housing **78** as depicted in cross-section in FIG. **15**. The sheath **72** connects with the slider **76**. Displacement of the slider **76** connected to sheath **72** relative to the slidable housing **77** connected to hypotube **66** and thus connected to capturing device **64**, displaces the sheath **72** relative to the forceps-needle combination **71**, thus enabling the extension, as depicted in FIG. **12**, and retraction as depicted FIG. **16**. The hypotube **66** secures to a proximal end **80** of the slidable housing **77** so that displacement of the slidable housing **77** and the slider **76** together displaces the forceps needle combination **71** and the sheath **72** relative to the distal end **62** of the tubular member **61** (FIGS. **12** and **17**). A proximal end **81** of the hypotube **66** in this embodiment includes an injection hub **82**.

In operating the apparatus **60**, the physician preferably positions the tubular member **61** to extend from the working channel of an endoscopic device **100** previously inserted in a patient. The physician manipulates the slider **74** and the slidable housing **77** and the slider **76** to extend the snare **70** and the forceps-needle combination **71** over a polyp **85**, as depicted in FIG. **12**. If the polyp **85** is a relatively small, flat polyp of a type that is usually difficult to sever and/or retrieve by prior art apparatus, the physician positions the snare **70** to encompass a base **86** of the polyp **85** and pierces the polyp **85** with the needle **71A** between the base **86** and a free end **87** of the polyp **85** to inject a suitable fluid (e.g., a saline solution or sclerotherapy agents) into the polyp **85** from the injection hub **82** to expand and swell the polyp **85**. The physician then closes forceps legs **71B** of the forceps needle combination **71** to capture the now swollen polyp **85** by distal displacement of the sheath **72** relative to the forceps legs **71B** (FIG. **16**). Retraction of the snare **70** severs the polyp **85** so that the forceps-needle combination **71** retains the severed portion including the free end **87**. Retracting the slidable housing **77** and distal displacing the slider **76**, as shown in FIG. **17**, moves the forceps-needle combination **71** into close proximity of the distal end **62**.

FIGS. **18** and **19** depict distal portions of the apparatus **60** with alternative capturing devices **64A** and **64B**, respectively. The embodiment of FIG. **18** includes only a forceps device **89** with extending legs **90**. Those skilled in the art will understand that in this case the hypotube **66** can be solid and that the sheath **22** can, alternatively, be omitted so that the legs **90** expand and contract upon extension and retraction relative to the distal end **62** of the tubular member **61**. Additionally, the hypotube **66** can be connected to a slider suitably mounted in a handle (not shown) similarly to the slider **74** of FIG. **12** with the slidable housing **77** of FIG. **12** also omitted.

The capturing device **64** of the embodiment of FIG. **19** includes only a needle **91** without any forceps device. The needle **91** operates substantially the same as the needle **71A** of the embodiment of FIG. **12**. That is, it connects with a proximal slidable member (not shown) to extend and retract the needle **91** and includes a means for enabling a fluid to be injected through the needle **91**. The needle **91** further includes one or more barbs **92** or other similar surface features formed thereon proximate its distal end. The barbs **92** tend to retard withdrawal of the needle **91** from the polyp **85**. Consequently, the polyp **85** tends to remain on the needle **91**.

Thus, after severing the polyp **85** by the snare **70**, the severed portion polyp **85** including the free end **87** can be removed by withdrawal of the elongated tubular member **61**. This embodiment also enables the collection of additional polyps by successively extending and positioning the snare **70** and needle **91** and then retracting the snare **70**, as discussed above. That is to collect an additional selected polyp, such as the polyp **85** after collecting polyps **85B** and **85A**, respectively, the user positions the distal end of the device proximate the polyp **85** and extends the snare **70** to encompass the polyp and the needle **91** to pierce the polyp. Upon piercing the selected polyp **85**, previously severed polyps retained on the needle **91** are urged proximally along the needle **91**. The user can then inject the polyp **85** with a suitable solution, if desired, prior to severing the polyp **85** by retracting the snare **70**. Once severed, the polyp **85** would be retained on the needle **91** as described above. Thus, as illustrated in FIG. **19A**, a plurality of polyps severed and retained in the sequential order of the polyps **85B**, **85A**, **85** are retained proximate the distal end of the needle **91**.

In summary, there have been described various embodiments of devices for severing and capturing polyps without prior art surgical intervention. Specifically, these devices include a catheter or like elongated tubular member having one or more lumens therein adapted for extending through the working channel of an endoscopic device having a viewing channel. Severing and capturing devices connect with control apparatus at the proximal end of the catheter to enable extension and retraction of the severing and capturing device relative to the distal end of the catheter. This structure

enables a physician to selectively grasp a polyp, sever a portion of the polyp from its base and withdraw the polyp from the patient. The severing device typically includes a snare. The capturing device may comprise a closed end clip, legs arranged in a forceps-like configuration, a barbed needle, or combination thereof. A needle can also allow a physician to inject fluid into a polyp thereby to enlarge the polyp and facilitate its severing and its removal.

Those skilled in the art will further appreciate that the described devices can be relatively easily constructed according to known methods and relatively easily used by physicians familiar with prior art devices. However, this invention provides physicians with devices that are more versatile in dealing with polyps and that are relatively easily used while also providing greater surety in retention of the portions of polyps that are severed as compared with the prior art devices. This invention has been disclosed in terms of certain embodiments. It will be apparent that many modifications can be made to the disclosed apparatus without departing from the invention. Therefore, it is the intent of the appended claims to cover all such variations and modifications as come within the true spirit and scope of this invention.

What is claimed as new and desired to be secured by Letters Patent of the United States is:

1. An apparatus for severing and retrieving a polyp for withdrawal from a patient comprising:

a catheter extending between a distal end tip and a proximal end, for positioning proximate a polyp;

a self-expansible severing and capturing device for retrieving a polyp, said severing and capturing device being extensible from said distal end of said catheter in an expanded form and retractable into said distal end in a compacted form; and

a control device at the proximal end of said catheter for selectively extending and retracting said severing and capturing device relative to said distal end of said catheter, wherein said severing and capturing device includes a continuous wire defining in the expanded form a first plane and at least one leg that is fixed directly to and that distally extends past the continuous wire, has a free end, and generally lies outside the first plane.

2. The apparatus for severing and retrieving a polyp as recited in claim 1 wherein said control device includes an axially stiff, laterally flexible cable extending through said catheter, and said continuous wire and said leg connects to the distal end of said cable.

3. The apparatus of claim 1, wherein said severing and capturing device includes a plurality of legs.

4. The apparatus of claim 3, wherein each of said plurality of legs has an inwardly directed finger proximate the distal ends of said legs.

5. The apparatus of claim 1, wherein said continuous wire defines in said expanded form an open loop.

6. The surgical instrument of claim 3, wherein said plurality of legs extend distally past the snare from opposed portions of said snare intermediate a distal end of said snare and said distal end of said cable.

7. A surgical instrument for severing and capturing a polyp, the instrument comprising:

an elongated tubular member having a distal end;

a snare for extension in an enlarged condition in a first plane from and retraction in a compact condition into said distal end of said tubular member;

a control device for selectively extending said snare relative to said distal end so as to enable positioning said snare to encompass a polyp, and for selectively retracting said snare relative to said distal end so as to sever such polyp;

and a capturing device connected to said control device such that said capturing device is extended with said snare, wherein upon retraction of the snare by said control device said capturing device grasps the polyp outside the first plane so that upon severing of the polyp by said snare said capturing device retains the severed portion of the polyp, wherein said capturing device includes at least one leg fixed directly to and extending distally past the snare and having a free end.

8. An instrument as recited in claim 7 wherein said at least one leg is a plurality of spaced legs.

9. A surgical instrument as recited in claim 7, wherein said leg has an inwardly directed finger proximate the distal end of said leg.

10. An apparatus for severing and retrieving a polyp comprising:

a catheter extending between a distal end and a proximal end;

a severing and capturing device for retrieving a polyp, said severing and capturing device being extensible from said distal end of said catheter in an expanded form and retractable into said distal end in a compacted form; and

a control device operably connected to the severing and capturing device to selectively extend and retract said severing and capturing device relative to said distal end of said catheter, said control device including an elongated control member extending through said catheter, said elongated control member supporting said severing and capturing device at a distal end of said elongated control member, wherein said severing and capturing device includes a continuous wire substantially defining in the expanded form a first plane, and said severing and capturing device includes a plurality of legs, each leg being fixed directly to and extending distally past the continuous wire and having a free end.

11. The apparatus of claim 10, wherein said continuous wire in the expanded form defines an open loop.

12. The apparatus of claim 10, wherein said plurality of legs in the expanded form generally lie outside the first plane.

13. The apparatus of claim 10, wherein said legs connect to the distal end of said elongated control member.

14. A surgical instrument for severing and capturing a polyp, the instrument comprising:

an elongated tubular member having a distal end;

a snare configured for extension in an enlarged condition substantially in a first plane from and retraction in a compact condition into said distal end of said tubular member;

a capturing device configured for extension substantially outside of said first plane from and retraction into said distal end of said tubular member, said capturing device including at least one leg that is fixed directly to and extends distally past the snare and has a free end; and

a control device having an elongated control member for supporting said snare and said capturing device at a distal end of said elongated control member, said control device configured for selectively extending said snare and said capturing device relative to said distal end of said tubular member so as to enable positioning said snare to encompass a polyp and for selectively retracting said snare and said capturing device relative

to said distal end of said tubular member so as to sever such polyp with said snare and to grasp such polyp with said capturing device outside the first plane.

15. The instrument of claim **14**, wherein said at least one leg has a finger proximate the distal end of said leg.

16. The instrument of claim **14**, wherein said capturing device includes a plurality of spaced legs extending from opposed portions of said snare intermediate a distal end of said snare and said distal end of said elongated control member.

17. The instrument of claim **16**, wherein at least one of said plurality of spaced legs has an inwardly directed finger proximate the distal end of said at least one of said plurality of spaced legs .

18. A surgical instrument for severing and capturing a polyp, the instrument comprising:

an elongated tubular member having a distal end;

a snare configured for extension in an enlarged condition substantially in a first plane from and retraction in a compact condition into said distal end of said tubular member;

a capturing device configured for extension substantially outside of said first plane from and retraction into said distal end of said tubular member, said capturing device including at least one leg; and

a control device having an elongated control member for supporting said snare and said capturing device at a distal end of said elongated control member, said control device configured for selectively extending said snare and said capturing device relative to said distal end of said tubular member so as to enable positioning said snare to encompass a polyp and for selectively retracting said snare and said capturing device relative to said distal end of said tubular member so as to sever such polyp with said snare and to grasp such polyp with said capturing device outside the first plane, wherein said capturing device includes a plurality of spaced legs extending from opposed portions of said snare intermediate a distal end of said snare and said distal end of said elongated control member, and wherein at least one of said plurality of spaced legs has an inwardly directed finger proximate the distal end of said at least one of said plurality of spaced legs.

19. An apparatus for severing and retrieving a polyp for withdrawal from a patient comprising:

a catheter extending between a distal end tip and a proximal end, for positioning proximate a polyp;

a self-expansible severing and capturing device for retrieving a polyp, said severing and capturing device being extensible from said distal end of said catheter in an expanded form and retractable into said distal end in a compacted form; and

a control device at the proximal end of said catheter for selectively extending and retracting said severing and capturing device relative to said distal end of said catheter, wherein said severing and capturing device includes a continuous wire defining in the expanded form a first plane and at least one leg that distally extends past the continuous wire and generally lies outside the first plane, wherein said severing and capturing device includes a plurality of legs, and wherein each of said plurality of legs has an inwardly directed finger proximate the distal ends of said legs.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,171,315 B1

DATED : January 9, 2001

INVENTOR(S) : **Michael S.H. Chu**, Brookline; **Yem Chin**, Burlington, both of MA (US)

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Claim 14, column 10, line 59, "extends" should read --extending--.

Claim 17, column 11, line 14, "legs ." should read --legs.--.

Signed and Sealed this

Twenty-second Day of May, 2001

Attest:

Nicholas P. Godici

NICHOLAS P. GODICI

Attesting Officer

Acting Director of the United States Patent and Trademark Office

United States Patent [19]

Komiya

[11] **4,011,872**

[45] **Mar. 15, 1977**

[54] **ELECTRICAL APPARATUS FOR TREATING AFFECTED PART IN A COELOMA**

[75] Inventor: **Osamu Komiya, Hachioji, Japan**

[73] Assignee: **Olympus Optical Co., Ltd., Tokyo, Japan**

[22] Filed: **Mar. 28, 1975**

[21] Appl. No.: **563,071**

[30] **Foreign Application Priority Data**

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Apr. 1, 1974 Japan 49-37270

[52] **U.S. Cl.** **128/303.14; 128/321**
[51] **Int. Cl.²** **A61B 17/36**
[58] **Field of Search** 128/303.14, 303.13, 128/303.15-303.18, 407-409, 321

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Primary Examiner—Robert W. Michell
Assistant Examiner—Lee S. Cohen
Attorney, Agent, or Firm—Ostrolenk, Faber, Gerb & Soffen

[57] **ABSTRACT**

An apparatus comprises an electrode operating member which is disposed within the distal end portion of an electrically insulating flexible tube which is adapted to be inserted into a coeloma. A plurality of electrodes for treating an affected part are attached to the electrode operating member, which is in turn moved by an operating wire passing through the tube, thereby enabling a movement of the electrodes out of or back into an opening formed in the end of the flexible tube. A high frequency current is supplied to the electrodes through the operating wire or a separate power cable.

10 Claims, 17 Drawing Figures

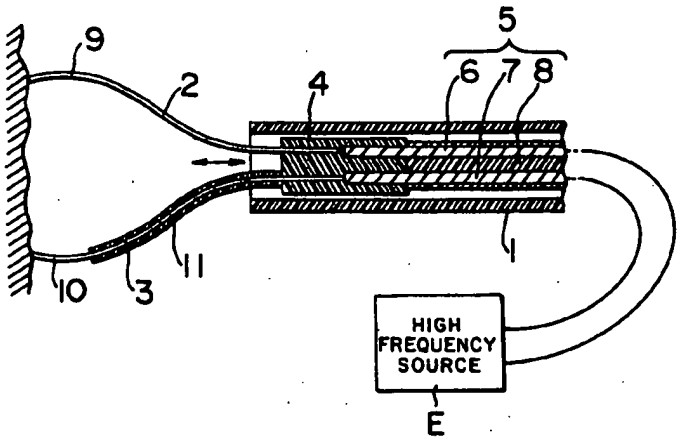


FIG. 1

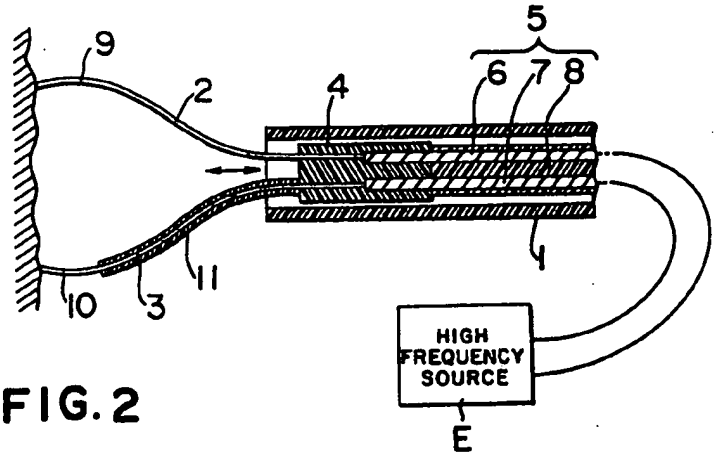


FIG. 2

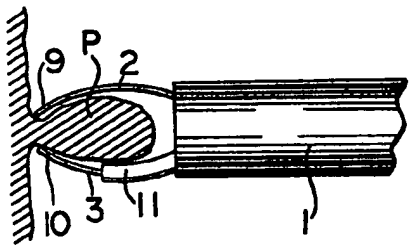


FIG. 3

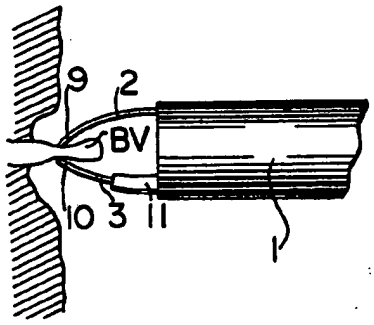


FIG. 4

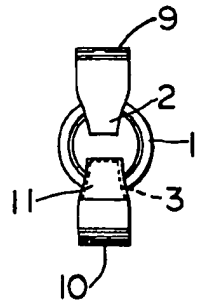


FIG. 5

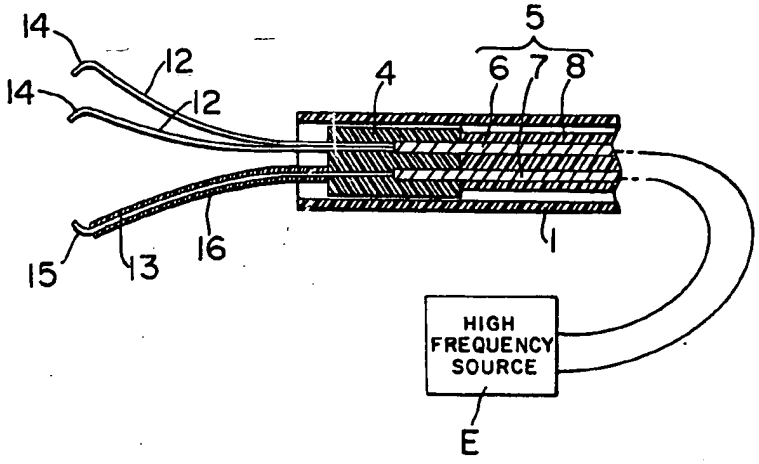


FIG. 6

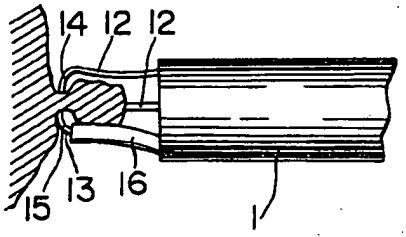


FIG. 7

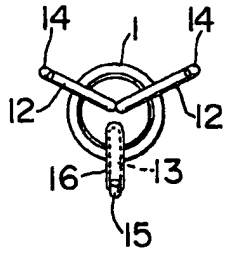


FIG. 8

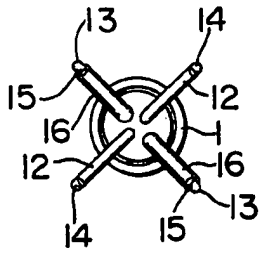


FIG. 9

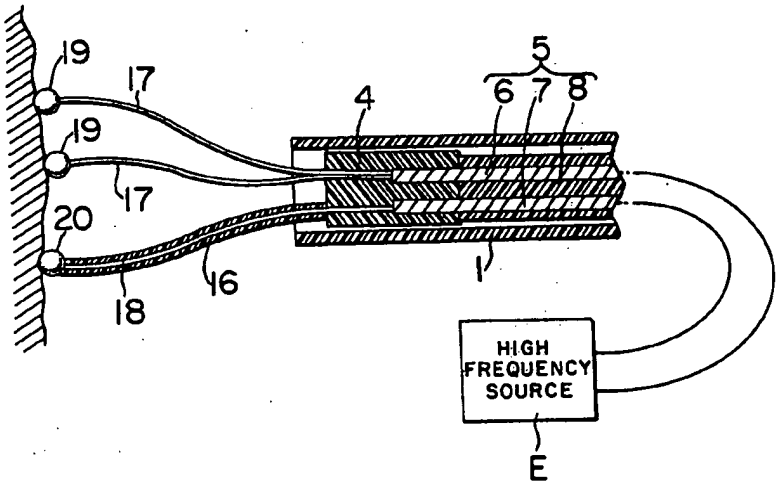


FIG. 10

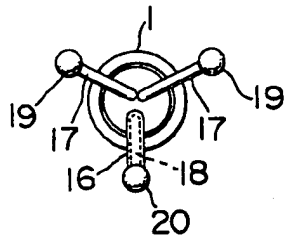


FIG. 11

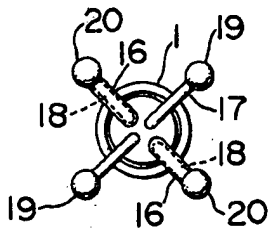


FIG. 12

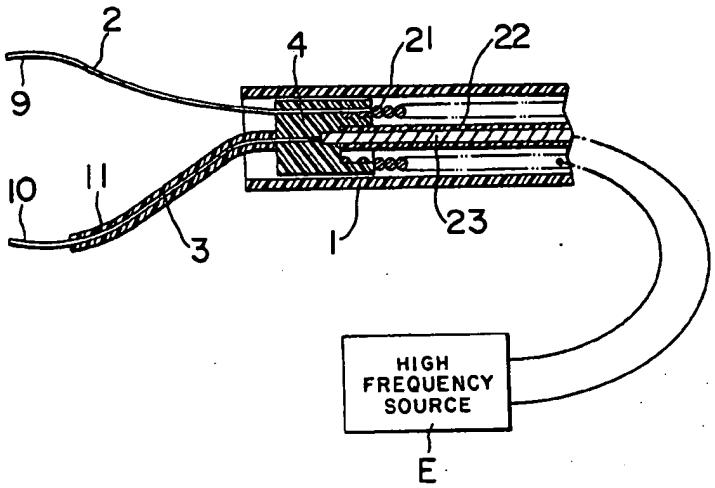


FIG. 13

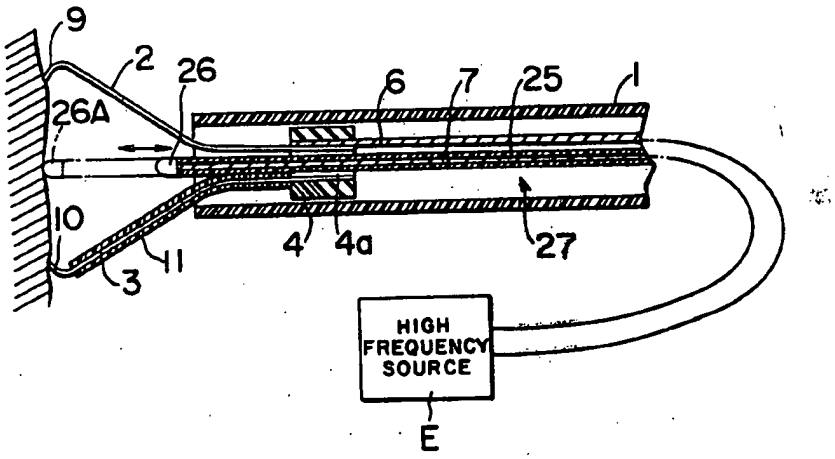

9
2
26
26A
6
7
25
1
10
11
3
4
4a
27
HIGH FREQUENCY SOURCE
E

FIG. 14

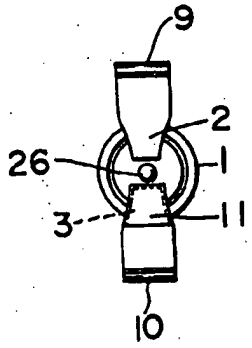

9
2
26
1
3
11
10

FIG. 15

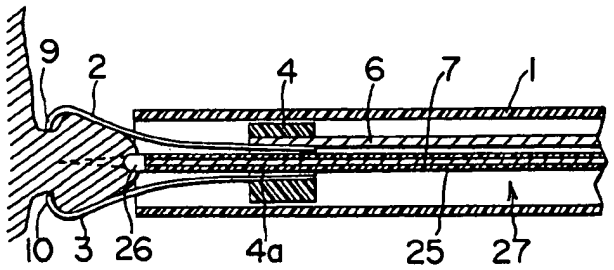


FIG. 16

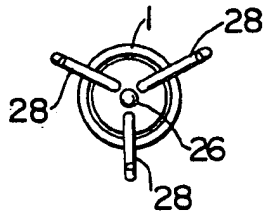
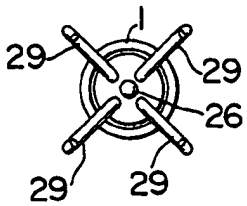


FIG. 17



ELECTRICAL APPARATUS FOR TREATING AFFECTED PART IN A COELOMA

BACKGROUND OF THE INVENTION

The invention relates to an electrical apparatus for treating an affected part in a coeloma, and more particularly to an electrical apparatus for surgically treating an affected part in a coeloma of a human body with a high frequency current.

An electrical apparatus for surgically treating diseased tissue by the use of a high frequency current is commonly known as a radio knife, and has been used only for the treatment of the exposed affected part of a physical body. However, with the recent development of endoscopes for examining the interior of a coeloma, a high frequency treatment of an affected part within a coeloma is contemplated. A radio knife which is designed to this end comprises a single treating electrode which is introduced into the coeloma, while the other electrode is brought in contact with the skin of a patient over an extensive area, thereby concentrating the electric current in the region of contact of the treating electrode for the purpose of excision, erasion or coagulation of the tissue in such region. However, such apparatus has an unsatisfactory efficiency and treating capability, and is also limited in the shape and number of treating electrodes, whereby inconveniences are experienced in providing a desired treatment effectively. Specifically, a large spacing between the electrodes may cause a cautery of tissues other than the affected one which need not be cauterized. Thus, the apparatus suffers from the inability of providing a localized treatment.

SUMMARY OF THE INVENTION

It is an object of the invention to provide an electrical apparatus for treating an affected part in a coeloma including a plurality of electrodes for treating affected part, which electrodes are all introduced into a coeloma by passing them through an electrically insulating flexible tube and which are supplied with a high frequency current through a power cable that is also passed through the flexible tube, the maneuvering of the treating electrodes being improved through the use of an operating wire to thereby produce an effective high frequency treatment of the affected part in a coeloma.

In accordance with the invention, an electrode operating member provided with a plurality of treating electrodes is mounted in the distal end portion of an electrically insulating flexible tube which is introduced into a coeloma, and the electrodes are supplied with a high frequency current from a high frequency source through a power cable which is also passed through the flexible tube. In accordance with the invention, a maneuvering of the treating electrodes within the coeloma is achieved in a facilitated manner, and the localized treating capability is increased, eliminating the disadvantage of cauterizing deep tissues which do not require cautery. At least one of the treating electrodes which is connected with one terminal of the high frequency source is coated with an electrically insulating material except for its end portion which remains exposed for contact with the tissue in the coeloma, thus preventing a direct contact between the treating electrodes and assuring an effective localized treatment of only an intended part. It is found that the treated tissue recovers rapidly.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross section of the electrical apparatus for treating affected part in a coeloma which is constructed in accordance with a first embodiment of the invention;

FIGS. 2 and 3 are similar views to FIG. 1, illustrating the operation of the apparatus shown in FIG. 1;

FIG. 4 is a front view of the forward portion of the apparatus shown in FIG. 1;

FIG. 5 is a cross section of the electrical apparatus for treating affected part in a coeloma which is constructed in accordance with a second embodiment of the invention;

FIG. 6 is a similar view to FIGS. 2 and 3, but illustrating the operation of the apparatus shown in FIG. 5;

FIGS. 7 and 8 are front views, illustrating two arrangements of the apparatus shown in FIG. 5 and having different numbers of the treating electrodes;

FIG. 9 is a cross section of the electrical apparatus for treating affected part in a coeloma which is constructed in accordance with a third embodiment of the invention;

FIG. 10 is a front view of the forward portion of the apparatus shown in FIG. 9;

FIG. 11 is a front view of an apparatus similar to that shown in FIG. 9, but having a different number of electrodes;

FIG. 12 is a cross section of the electrical apparatus for treating affected part in a coeloma which is constructed in accordance with a fourth embodiment of the invention;

FIG. 13 is a cross section of the electrical apparatus for treating affected part in a coeloma which is constructed in accordance with a fifth embodiment of the invention;

FIG. 14 is a front view of the forward portion of FIG. 13;

FIG. 15 is a cross section of the apparatus shown in FIG. 13, illustrating the operation thereof; and

FIGS. 16 and 17 are front views of modifications of the embodiments of FIG. 15.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT OF THE INVENTION

FIG. 1 is a cross section of the electrical apparatus for treating an affected part in a coeloma which is constructed in accordance with a first embodiment of the invention. The apparatus includes an electrically insulating flexible tube 1 which is shaped so that it can be introduced into a coeloma by passing it through a forceps channel of an endoscope. A plurality of electrodes 2, 3 for treating an affected part is attached to an electrode operating member 4, which electrodes 2, 3 are mounted in the forward end of the flexible tube 1. The electrode operating member 4 comprises an electrically insulating material and is mechanically connected with a power cable 5 which passes through the flexible tube 1. At its other end, the power cable 5 extends out of the flexible tube 1, and can be operated to advance or retract the electrode operating member 4 within the flexible tube 1. Thus, the power cable 5 functions as an operating wire. The cable 5 comprises a pair of electrically conductive wires 6, 7 which are connected with the terminals of a high frequency source E and which are covered with and integrally

molded with an electrically insulating resin 8 which both separates and surrounds wires 6 and 7.

The treating electrodes 2, 3 are formed of strips of electrically conductive material and attached to the electrode operating member 4 in opposing relationship with each other, with their forward free ends 9, 10 normally resiliently urged away from each other. As shown in FIG. 4, the portions of the electrodes 2, 3 inward from the forward free ends 9, 10 are more closely spaced than the forward free ends 9, 10. The forward free ends 9, 10 have a width which is slightly less than the internal diameter of the flexible tube 1 so that by pulling the power cable 5, the treating electrodes 2, 3 can be retracted into the flexible tube 1 together with the electrode operating member 4, the electrodes 2, 3 being then constrained by the edge of the opening of the tube 1 to be positioned closer to each other when the member 4 is drawn into tube 1. When the electrodes 2, 3 are pushed forward, they assume an open position shown in FIG. 1, by virtue of their inherent resilience. In order to increase the retention of tissue between the electrodes 2, 3, their forward ends 9, 10 are gently curved toward each other at their tips. The electrodes 2, 3 are electrically connected with the conductive wires 6, 7 of the power cable 5 within the electrode operating member 4. One of the treating electrodes, 3, is coated with an electrically insulating material 11 except for the forward end 10 which remains exposed. Thus, no direct contact occurs between the electrodes 2, 3 except for the forward ends 9, 10 which bear against the opposite sides of the tissue of an affected part.

In use, the operating wire or the power cable 5 is pulled to retract the electrode operating member 4 together with the treating electrodes 2, 3 into the flexible tube 1, and the flexible tube 1 is passed through the forceps channel of an endoscope, for example, to move it to an intended region within a coeloma. Then the power cable 5 is externally operated to push forward the electrode operating member 4 as shown in FIG. 1, causing the treating electrodes 2, 3 to move out of the opening in the inner end of the flexible tube 1. The degree of opening of the treating electrodes 2, 3 depends on the amount of such movement. FIG. 1 illustrates the maximum opening, and at this time the electrodes 2, 3 are removed from contact with the edge of the opening in the flexible tube 1. Where a cautery and coagulation of the tissue in the coeloma is desired over a broad area, the electrodes 2, 3 are opened as shown in FIG. 1, and their forward free ends 9, 10 are brought into contact with the surface of the tissue, followed by energization thereof through the power cable 5 by operating the high frequency source E. Thereupon a high frequency current flows through the tissue portion lying between the forward ends 9, 10 of the electrodes 2, 3, producing a Joule's heat therein by virtue of the electrical resistance presented by the tissue portion, thereby accomplishing the cautery and coagulation of the tissue portion between the forward ends 9, 10. The spacing between the forward ends 9, 10 of the electrodes 2, 3 can be adjusted to any desired opening by pulling the cable 5 to cause the electrodes 2, 3 to bear against the edge of the opening in the flexible tube 1. In this manner, the area over which the cautery or coagulation is performed can be determined as desired. A cautery or coagulation of part of the tissue in the coeloma, such as polyp or blood vessel, can be achieved by holding the polyp P (FIG. 2) or blood vessel BV (FIG. 3) between the end portions 9, 10 and producing a current flow therebetween.

FIGS. 5 to 8 show a second embodiment of the invention in which a plurality of treating electrodes are all formed of rod-shaped resilient conductive material. FIG. 7 shows the use of three treating electrodes 12, 12, 13 while FIG. 8 shows the use of four electrodes 12, 12, 13, 13. As in the first embodiment, the electrodes 12, 13 are resiliently urged to assume an open position so as to be spaced apart from each other, and their forward ends 14, 15 are folded back toward each other. The electrode 13 or electrodes 13, 13 which are connected with one terminal of the high frequency source E are coated with an electrically insulating material 16 except for their forward ends 15 which remain exposed, thus minimizing the possibility of electrical contact with the other electrodes 12. In other respects, the arrangement and function are generally similar to those described in connection with the first embodiment.

FIGS. 9 to 11 show a third embodiment of the invention in which treating electrodes 17, 18 have their forward tips 19, 20 formed as spheres for increasing the area of contact with the tissue within the coeloma. Other features are similar to those described previously.

FIG. 12 shows a fourth embodiment of the invention, illustrating a modification of the power cable or operating wire which operates on the electrode operating member 4. Specifically, the cable comprises an electrically conductive coil 21 which is inserted into the flexible tube 1, and an electrically conductive wire 23 covered with an electrically insulating material 22 and passing inside the coil 21. The coil 21 and the wire 23 are secured to the electrode operating member 4 and are electrically connected with the electrodes 2, 3, respectively. In this manner, the overall flexibility of the device is increased, improving the maneuverability. In other respects, the arrangement and function are similar to those described previously in connection with the first and second embodiments.

FIGS. 13 and 14 show a fifth embodiment of the invention in which the electrode operating member 4 is mechanically connected with a conductive operating wire 6 which passes through the flexible tube 1. The wire 6 projects out of the other or opposite end of the flexible tube 1, and can be operated to cause a displacement of the electrode operating member 4. In addition, the wire 6 is electrically connected with both treating electrodes 2, 3. Thus the operating wire 6 constitutes one of the supply wires within the power cable. Another conductive operating wire 7 covered with an insulating material 25 passes through the center of the flexible tube 1, and extends through an opening 4a formed centrally in the electrode operating member 4 so that its forward end extends into the opening of the flexible tube 1. A treating electrode 26 formed of a conductive material and having a spherical configuration is attached to the extremity of the conductive operating wire 7. At its other end, the operating wire 7 also extends out of the other end of the flexible tube 1 to permit an advancing or retracting operation of the treating electrode 26. When the operating wire 7 is forced into the flexible tube 1, the treating electrode 26 can be projected into the space between the other treating electrodes 2, 3. The operating wire 7 constitutes the other supply wire of the power cable, and is electrically connected with the other terminal of the

source E for energizing the electrode 26. In the arrangement described, the wires 6, 7 serve as the supply wires of the power cable 27 while simultaneously functioning as the operating wires. Alternatively, the operating wires 6, 7 may be separate from the power cable 27 so as to serve only the electrode operating function.

In use, the respective treating electrodes 2, 3, 26 are initially retracted within the flexible tube 1, which is then inserted into the forceps channel of an endoscope, for example, for introducing it to an intended region within a coeloma. Subsequently, the operating wire 6 is externally operated to advance the electrode operating member 4 forward, thereby projecting the treating electrodes 2, 3 of one polarity out of the opening of the flexible tube 1. At this time, since the electrodes 2, 3 bear against the edge of the opening in the flexible tube 1, the degree of opening of the electrodes 2, 3 depends on the extent to which the electrodes 2, 3 are projected. In FIG. 13, the maximum separation distance between electrodes 2, 3 is shown, and under this condition, displaced from the left-hand edge of the opening in of the flexible tube 1. The degree of separation of these electrodes are adjusted according to the size of an area for which a cautery or coagulation treatment is desired. After such adjustment, the forward ends 9, 10 of the treating electrodes 2, 3 are brought into contact with the surface of the tissue in the coeloma. Subsequently, the operating wire 17 is externally operated to cause the treating electrode 26 of the opposite polarity to project through the opening in the flexible tube 1 so as to contact the surface of the tissue at a position intermediate the remaining electrodes 2, 3, as indicated in phantom lines 26A in FIG. 13. Then the source E is turned on to supply a high frequency current to the respective electrodes 2, 3, 26, whereupon the tissue portion lying between the electrodes 2, 3 and the electrode 26 are cauterized or coagulated by the Joule's heat produced.

FIG. 15 shows a modification in which part of the tissue in a coeloma is held between the forward ends 9, 10 of the treating electrodes 2, 3 of one polarity while the treating electrode 26 of the other polarity is applied against the top of the tissue for cautery and coagulation. In this manner, it is possible to produce a cautery and coagulation of the entire tissue portion which is held between the electrodes 2, 3. Such an arrangement is useful for the cautery and coagulation of an affected part, such as a polyp. The cauterized and coagulated tissue portion will be destroyed and the removed dead tissue falls down. An even more complete cautery of the tissue portion held between the electrodes 2, 3 can be achieved by providing the electrode 26 in the form of a needle, as indicated in broken lines in FIG. 15.

FIGS. 16 and 17 illustrate an arrangement in which a plurality of electrodes 28, 29 of one polarity are in the form of resilient conductive rods and cooperate with the centrally located electrode 26. It will be understood that these electrodes 28, 29 open to a degree dependent on the extent by which they project from the forward end of the flexible tube 1.

What is claimed is:

1. An electrical apparatus for treating an affected part in a coeloma comprising:

an electrically insulating, hollow, flexible tube having a distal end and a proximal end and adapted to be inserted into a coeloma and having an opening in its distal end;

an electrode operating member formed of an insulating material and having a first end facing said distal end of said flexible tube and a second end facing said proximal end of said flexible tube, said electrode operating member being slidably disposed within said flexible tube such that said electrode operating member can slide towards and away from said distal end of said flexible tube;

a plurality of treating electrodes each being formed of a resilient, conductive material, each of said treating electrodes having a free end and a base end, said base ends of said treating electrodes being attached to said first end of said electrode operating member, said free ends of said treating electrodes extending towards said opening in said flexible tube for movement out of and into said opening in said flexible tube in response to movement of said electrode operating member;

an operating wire extending from said proximal end of said flexible tube into said flexible tube and secured to said second end of said electrode operating member for causing displacement of said electrode operating member in response to displacement of said operating wire into and out of said flexible tube, said operating wire including power cable means for supplying a high frequency current to the treating electrodes.

2. An electrical apparatus according to claim 1 in which at least one of the treating electrodes is covered with an electrically insulating material over the length of said one electrode which is located externally of the electrode operating member except for the extreme end portion of the free end which remains exposed for cooperation with another one of the electrodes to hold a portion of a tissue in a coeloma therebetween, thus preventing direct contact between the cooperating electrodes.

3. An electrical apparatus according to claim 1 in which the tip of the free ends of each treating electrode is made spherical to increase the area of contact with a tissue in the coeloma.

4. An electrical apparatus according to claim 1 in which a pair of said treating electrodes are formed of conductive blades each including a free end of a width slightly less than the internal diameter of the flexible tube and a base end at which it is attached to the electrode operating member, the width of the base end being reduced as compared with the width of the free end, said electrodes being disposed in opposing relationship with each other and being resiliently urged so that their free ends are removed from each other, the tips of the free ends of the electrodes being curved toward each other.

5. The apparatus of claim 1 further comprising an additional electrode extending through said operating member and having a first end movable into and out of said opening independently out of said operating member;

said power cable means including a wire connected to the opposite end of said additional electrode for moving said additional electrode and for supplying electric power thereto.

6. The apparatus of claim 5 wherein at least two electrodes are secured to said operating member and electrically connected in common;

the first end of said additional electrode being positioned so that the tip thereof is positioned between the tips of the free ends of said two electrodes.

7. An electrical apparatus for treating an affected part in a coeloma comprising:

an electrically insulating flexible tube having a distal end and a proximal end and adapted to be inserted into a coeloma, said flexible tube having an opening in its distal end;

an electrode operating member having a first end facing said distal end of said flexible tube and a second end facing said proximal end of said flexible tube, said electrode operating member being slidably disposed within said flexible tube such that said electrode operating member can slide towards and away from said distal end of said flexible tube;

a first and a second treating electrode, each of said treating electrodes having a free end and a base end, said base end of each of said treating electrodes being attached to said first end of said electrode operating member, said free end of each of said treating electrodes extending towards said opening in said flexible tube for movement out of or into said opening in the distal end of said flexible tube in response to movement of said electrode operating member;

a wire assembly extending from said proximal end of said flexible tube into said flexible tube and secured to said electrode operating member for causing displacement of said electrode operating member in response to displacement of said operating wire into and out of said flexible tube, said wire assembly including a helical conductive coil having a central opening therethrough and disposed within said flexible tube and having one end coupled to said first treating electrode for supplying a high frequency current to said first treating electrode, and a conductive wire spaced from and passing into said central opening in said conductive coil and being coupled to said second treating electrode for supplying high frequency current to said second treating electrode.

8. An electrical apparatus for treating an affected part in a coeloma, comprising:

an electrically insulating, hollow, flexible tube having a distal end and a proximal end, said tube being adapted to be inserted into a coeloma and having an opening in its distal end;

an electrode operating member having a central passage therethrough and having a first end facing said distal end of said flexible tube and a second end facing said proximal end of said flexible tube, said electrode operating member being slidably disposed within said flexible tube, such that said electrode operating member can slide towards and away from said distal end of said flexible tube;

a plurality of treating electrodes, each of said treating electrodes having a free end and a base end, said base end of each of said electrodes being attached to said first end of said electrode operating member, said free ends of said treating electrodes extending towards said opening in said flexible tube for movement out of or into said opening in said flexible tube in response to movement of said electrode operating member, said treating electrodes slidably engaging the periphery of said opening in said flexible tube;

a first operating wire extending from said proximal end of said flexible tube into said flexible tube and secured to said second end of said electrode operating member for causing displacement of said electrode operating member in response to displacement of said first operating wire into and out of said flexible tube;

a second operating wire extending from said proximal end of said flexible tube into said flexible tube and through said central passage in said electrode operating member, said second operating wire having a free end extending towards said opening in said flexible tube;

a treating electrode in addition to said plurality of treating electrodes attached to said free end of said second operating wire for movement out of or into said opening in said distal end of said flexible tube; and

means for supplying high frequency current to said treating electrodes.

9. An electrical apparatus according to claim 8 in which the plurality of treating electrodes are in the form of resilient rods which are formed so that their free ends are displaced from each other the tips of the free ends of the respective rods being curved toward one another.

10. An electrical apparatus according to claim 8, wherein the means for supplying current to the treating electrodes includes a power cable which is inserted into the flexible tube for supplying high frequency current to the treating electrodes.

* * * * *

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United States Patent [19]

McKeating

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[45] Date of Patent: May 5, 1998

[54] POLYPECTOMY INSTRUMENT

[76] Inventor: John A. McKeating, 1074 Osage Dr., Pittsburgh, Pa. 15235

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[51] Int. Cl.[6] A61B 17/24

[52] U.S. Cl. 606/114; 606/113; 606/110

[58] Field of Search 606/1, 110, 113, 606/114, 127, 128, 27, 32, 37, 39, 40, 45–50

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Primary Examiner—Glenn Dawson

Attorney, Agent, or Firm—Ansel M. Schwartz

[57] ABSTRACT

An instrument to perform endoscopic polypectomy having a first portion which grasps a polyp and a second portion which cuts away the polyps. The second portion is in contact with the first portion while the first portion grasps the polyp when the polyp is cut by the second portion. The first sheath member preferably contains a small grasping forcep mechanism. The second sheath member preferably contains a wire snare mechanism.

6 Claims, 2 Drawing Sheets

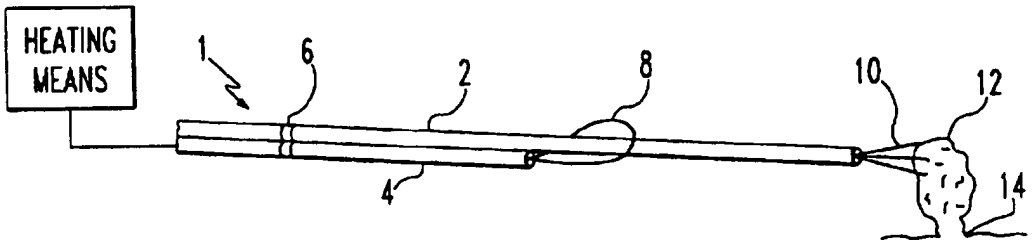

FIG. 1A
PRIOR ART

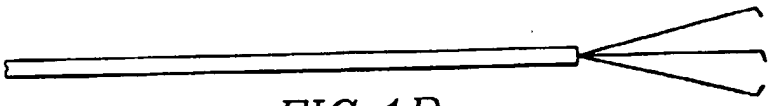

FIG. 1B
PRIOR ART

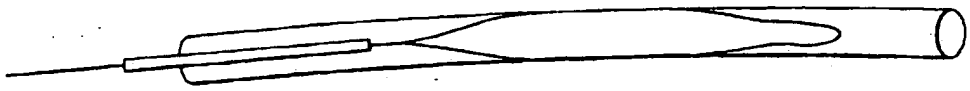

FIG. 1C
PRIOR ART

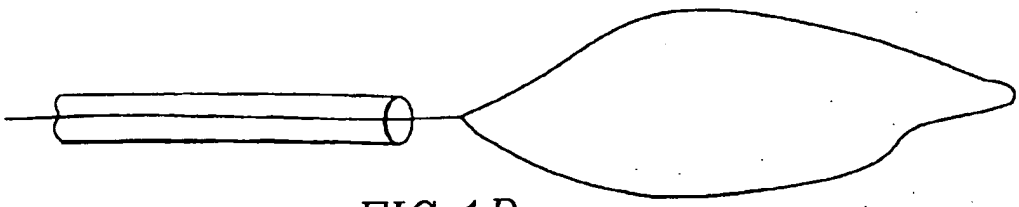

FIG. 1D
PRIOR ART

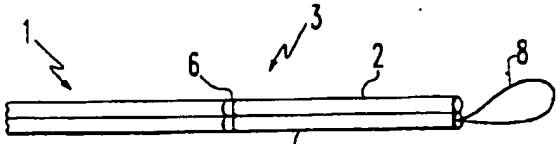

FIG.2A

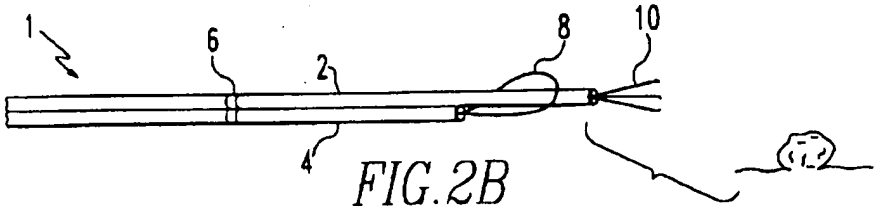

FIG.2B

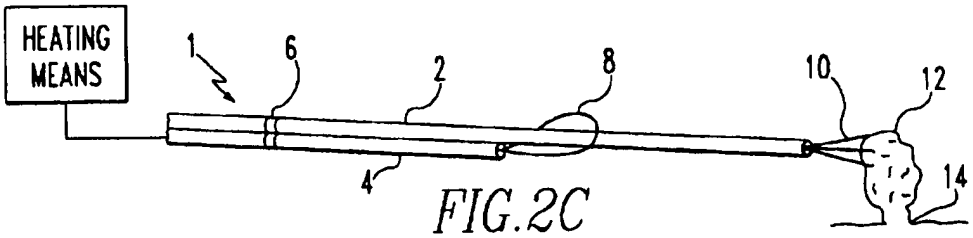

FIG.2C

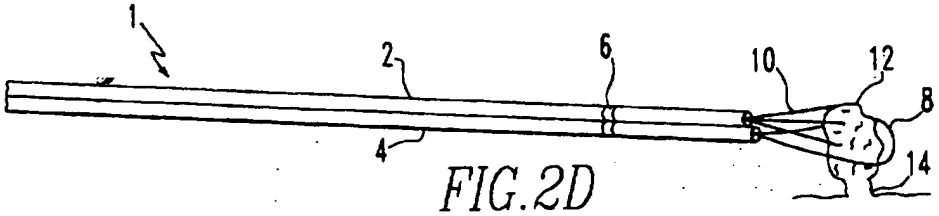

FIG.2D

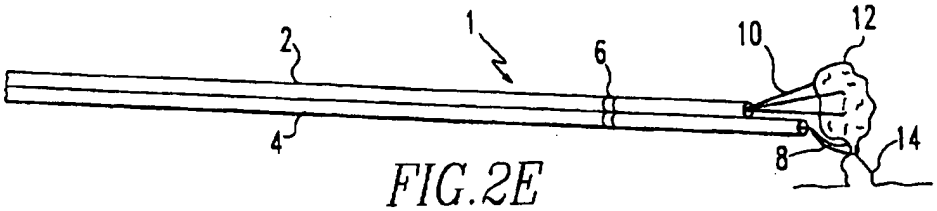

FIG.2E

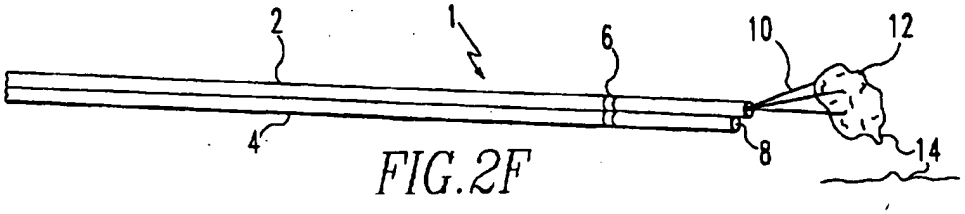

FIG.2F

POLYPECTOMY INSTRUMENT

FIELD OF THE INVENTION

The present invention is related in general to medical devices. More specifically, the present invention is related to an instrument for removing polyps.

BACKGROUND OF THE INVENTION

An endoscope is a long flexible tube with a fiber optic light source used to visualize the upper and lower gastrointestinal tract. Such an instrument is often used to search for and remove abnormal growths or polyps from the lining of these organs, particularly the colon. It has been well documented that colon cancer arises in polyps. In populations in which these mushroom-shaped growths have been aggressively sought and removed, the incidence of colon cancer has been reduced. An endoscope is employed to remove polyps with diameters measuring up to approximately one inch; an operation is generally required to extract larger polyps.

There are three basic types of instruments which can be passed down a hollow channel in an endoscope to remove tissue. The first, as shown in FIG. 1*a*, is a small-cup biopsy forcep. This instrument bites the tissue and is withdrawn into the biopsy channel, pulling with it a small fragment of tissue. While this biopsy forcep can remove very small polyps measuring a few millimeters, it can only biopsy larger lesions. The second instrument, one more suited to the complete removal of the polyp, is the polypectomy snare, as shown in FIGS. 1*c* and 1*d*. This is a long thin wire with a lasso at the end contained in a flexible plastic sheath. The endoscopist opens the snare by advancing the wire out of the sheath and closes the snare by pulling the wire back into the sheath. A third type of instrument, as shown in FIG. 1*b*, is the grasping forcep. The grasping forcep resembles the biopsy forcep in its scissor-like opening and closing action and is usually used to retrieve a polyp after removal.

To perform a polypectomy, the endoscopist advances the scope into the colon until the polyp is well visualized. The snare contained within the plastic sheath is then advanced down the endoscope's biopsy channel. The snare is then opened by advancing the wire through the sheath with a hand-held trigger mechanism. The snare must then be placed over the polyp and gradually tightened around the stalk. As the wire snare is gradually closed, electrical current is passed through the wire, allowing the snare to cut through the stalk in a bloodless fashion. The current is intended to coagulate any small blood vessels in the stalk of the polyp and prevent bleeding. The polyp is then retrieved and sent to the pathologist for evaluation to determine the presence of any cancer therein.

Invariably, the most difficult part of this procedure is getting the snare around the polyp. As one looks down the long tubular colon, the polyp may arise at the three o'clock axis and the snare may exit the endoscope at the nine o'clock axis. With the scope lying within up to six feet of the colon, it is difficult to change the axis. Although the last several centimeters of the scope are very flexible and are manipulated by turning knobs near the eyepiece, placement of the snare over the polyp is often a formidable task.

Another problem encountered during conventional polypectomy is that, once the snare is around the polyp, it is difficult for the endoscopist to tell how close to the wall of the bowel the snare is positioned. Whereas a superficial positioning may result in incomplete removal of a cancerous polyp, an aggressive positioning may cause perforation of the bowel wall with potentially disastrous consequences. Finally, after the stalk is cut, retrieval of the polyp is difficult. Although a grasping forcep can be employed in an attempt to grasp the loose polyp, it is not uncommon for transected polyps to be lost, thus making diagnosis impossible.

The present invention allows a polyp to be grasped so it is not lost when it is separated from the colon, and to be separated from the colon in a safe and effective manner.

SUMMARY OF THE INVENTION

The present invention is an instrument to perform endoscopic polypectomy. The instrument comprises a first portion which grasps a polyp and a second portion which cuts away the polyp. The second portion is in contact with the first portion when the polyp is cut by the second portion while the first portion grasps the polyp. Preferably, the first portion comprises a first sheath member having a small grasping forcep and the second portion comprises a second sheath member having a wire snare. The wire snare is preferably constructed with "memory" so that when it is advanced through the second sheath, it bends toward the first sheath member.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings, the preferred embodiment of the invention and preferred methods of practicing the invention are illustrated in which:

FIGS. 1*a*–1*d* are schematic representations showing prior art instruments.

FIGS. 2*a*–2*f* are schematic representations illustrating the operation of the instrument.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings wherein like reference numerals refer to similar or identical parts throughout the several views, and more specifically to FIGS. 2*a*–2*f* thereof, there is shown an instrument 1 to perform endoscopic polypectomy. The instrument 1 comprises a first portion which grasps a polyp and a second portion which cuts away the polyp. The second portion is in contact with the first portion when the polyp is cut by the second portion while the first portion grasps the polyp. Preferably, the first portion comprises a sheath member 2 having a small grasping forcep 10, such as that sold by Positrap™ polyp retriever, produced by Microvasive (Boston Scientific Corporation), Watertown, Mass. Preferably, the second portion comprises a sheath member 4 having a wire snare 8 such as that sold by Captivator™ single use polypectomy snare, produced by Microvasive (Boston Scientific Corporation), Watertown, Mass. The wire snare 8 is preferably constructed with memory so that when it is advanced through the sheath member 4, it bends toward sheath member 2 as it opens, as shown in FIG. 2*a*. As shown in FIG. 2*b*, the grasping forcep 10 is then advanced through the wire snare 8 to grasp the polyp 12, as shown in FIG. 2*c* away from the wall of the colon. The wire snare 8 is then advanced over the polyp 12, as shown in FIG. 2*d*. The polyp 12 can then be pulled with the forcep 10 and cut, as shown in FIG. 2*e* with the snare 8 at a point just below where the polyp is attached to the colon wall. The snare 8 preferably has an electric current which cauterizes the incision. The polyp 12 can then be removed, as shown in FIG. 2*f* by maintaining forcep 10 in a grasping position about the severed polyp 12 as the instrument 1 is withdrawn from the colon.

The instrument 1 has at least three very important advantages. First, traction, as shown in FIG. 2e, may be placed on the polyp 12 to pull it away from the wall 14 of the organ, allowing accurate placement of the wire snare 8 under direct visualization with an endoscope to minimize the risks of perforation and incomplete removal of the polyp 12. Secondly, the wire snare 8 is advanced around sheath member 2 so that it must lasso the polyp 12 as it is advanced. This automatic lassoing feature greatly expedites the lassoing of the polyp 12 and makes the entire procedure shorter, safer and less painful with decreased manipulation of the endoscope. Finally, retrieval of the transected polyp 12 is assured by secure purchase of the grasping forceps 12. It should be noted that the size of the diameter of the sheaths 2, 4 must be miniaturized in order to allow passage down a standard endoscope biopsy channel.

In a specific embodiment, sheaths 2, 4 are comprised of silastic and have an outer diameter suitable to fit down the biopsy channel. The channel typically measures about 3.2 mm but most of the instruments are about 2.3 mm. The sheaths 2, 4 have a combined outer diameter of preferably 2.5 mm. The sheath members 2, 4 are connected with a connecting member 6 which allow the sheath members 2, 4 to slide relative to each other during operation. The connecting member 8 preferably has the form of a FIG. 8, with the sheath members inserted through the respective loop of the 8. The connecting member can be made of plastic with the loops forming a tight fit with the members to maintain them in secure relation so they do not wiggle in the loops of the connecting member 6, but such that they can slide in the loops. Preferably, the connecting member 6 is fixed to the first sheath member 2 but in sliding contact with the second sheath member 4, so the second sheath member 4 can be advanced to allow the snare 8 to be placed about the polyp 12 at the proper time.

In the operation of the preferred embodiment, an instrument 10 intended for endoscopic removal of intestinal polyps is comprised of a grasping type forcep 10 and a snare 8 juxtaposed and designed to work in concert with the grasping forcep 10. There are two side-by-side sheaths 2, 4, which, although mechanically coupled, have some ability to slide along each other. These sheaths may be configured so that the contour of each is semi-circular and together the contours form a round cylinder. The first sheath 2 contains a grasping forcep 10 and a second sheath 4 contains a snare 8. This instrument 10 is placed down the hollow channel in the endoscope and advanced to the area of the colon containing the polyp 12. With the polyp 12 in view, the snare 8 is partially advanced from its sheath 4. The wire of the snare 8 is constructed with a "memory" so that as it is advanced, it opens and bends toward the first sheath 2 containing the grasping forcep 10. The grasping forcep 10 is then advanced to the polyp 12 and opened and the polyp 12 is grasped. With the grasping forcep 10 in place and engaged with the polyp 12, gentle traction is placed on the polyp 12. This serves to distract the polyp 12 away from the wall of the intestine 14 and elongate the stalk of the polyp 12. The grasping forcep 10 now acts as a "post" to direct the snare 8 to and over the polyp 12. With the grasping forcep 10 in place, the snare 4 cannot miss the polyp 12. The traction and elongation of the stalk allow for precise placement of the snare around the stalk of the polyp 12 with much better visualization. As the snare 8 is gradually tightened around the stalk of the polyp 12 electrical current is passed through the wire as described above. When the snare 8 has completely cut through the stalk of the polyp 12, the grasping forcep 10 remains firmly attached to the polyp 12. This ensures removal of the polyp 12 and prevents the loss of a loose polyp 12. The endoscope and the instrument 10 are removed from the intestine as a unit and the polyp 12 is sent for pathologic examination. A thin colored stripe is placed along the side of each of the sheaths 2, 4 so that if the endoscopist wishes to change the orientation of the instrument 10, it can be withdrawn from the scope and replaced in a different orientation.

Although the invention has been described in detail in the foregoing embodiments for the purpose of illustration, it is to be understood that such detail is solely for that purpose and that variations can be made therein by those skilled in the art without departing from the spirit and scope of the invention except as it may be described by the following claims.

What is claimed is:

1. A cut and retrieval instrument comprising:

a first portion which is adapted to grasp a polyp, said first portion includes a first sheath member having a grasping forcep slidably disposed within said first sheath member; and

a second portion which is adapted to cut away the polyp, said second portion connected to the first portion, said second portion includes a second sheath member disposed adjacent to the first sheath member having a wire snare with a snare loop slidably disposed within said second sheath member such that the grasping forcep can slide relative to the first sheath member through the snare loop of the wire snare when the snare loop extends from the second sheath member, said loop trained into a bent configuration which upon its advancement out of the second sheath bends towards the forcep so the forcep slides through the loop.

2. An instrument as described in claim 1 wherein the snare loop is comprised of a material having shape memory so as the snare loop bends towards the first sheath member the grasping forcep can slide relative to the first sheath member through the snare loop of the wire snare when the snare loop extends from the second sheath member.

3. An instrument as described in claim 2 wherein the wire snare includes means for heating the snare loop.

4. An instrument as described in claim 3 including a connector member slidably connecting the first sheath member to the second sheath member to allow the first sheath member to slide relative to the second sheath member.

5. An instrument as described in claim 3 wherein the first and second sheath members define an envelope which has a maximum outer dimension less than 1 inch to fit into an endoscope biopsy channel.

6. A method for removing a polyp from a wall of a colon comprising the steps of:

grasping the polyp with a forcep housed in a first sheath member;

pulling the polyp so it moves away from the colon wall;

moving a wire snare over the forcep grasping the polyp until the wire snare is essentially below the polyp and above the colon wall;

closing the wire snare until the polyp is cut from the colon wall; and

removing the forcep grasping the polyp from the colon.

* * * * *

United States Patent [19]

Yoon

[11] **Patent Number: 4,935,027**

[45] **Date of Patent: Jun. 19, 1990**

[54] **SURGICAL SUTURE INSTRUMENT WITH REMOTELY CONTROLLABLE SUTURE MATERIAL ADVANCEMENT**

[76] Inventor: **Inbae Yoon**, 2101 Highland Ridge Dr., Phoenix, Md. 21131

[21] Appl. No.: **396,340**

[22] Filed: **Aug. 21, 1989**

[51] **Int. Cl.**[5] **A61B 17/06**

[52] **U.S. Cl.** **606/146**; 606/148

[58] **Field of Search** 606/146, 113

[56] **References Cited**

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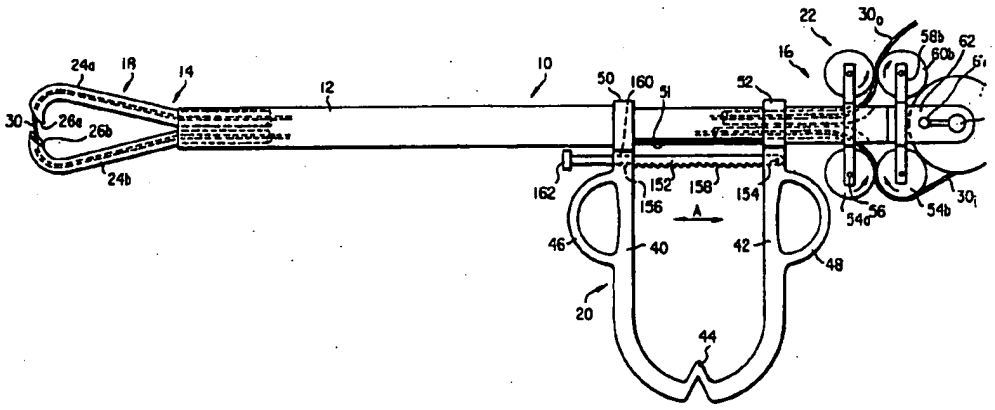
Primary Examiner—Randall L. Green
Assistant Examiner—Gary Jackson
Attorney, Agent, or Firm—Venable, Baetjer & Howard

[57] **ABSTRACT**

The invention relates to surgical instruments and methods for effecting suturing of tissue that can be controlled from a position remote from the suture site. The invention provides for the continuous feed of suture material through opposed forcep jaw members between which the tissue segments are interposed to expedite the suturing process and enable suturing to be accomplished at remote internal sites of the body incident to various endoscopic procedures.

55 Claims, 5 Drawing Sheets



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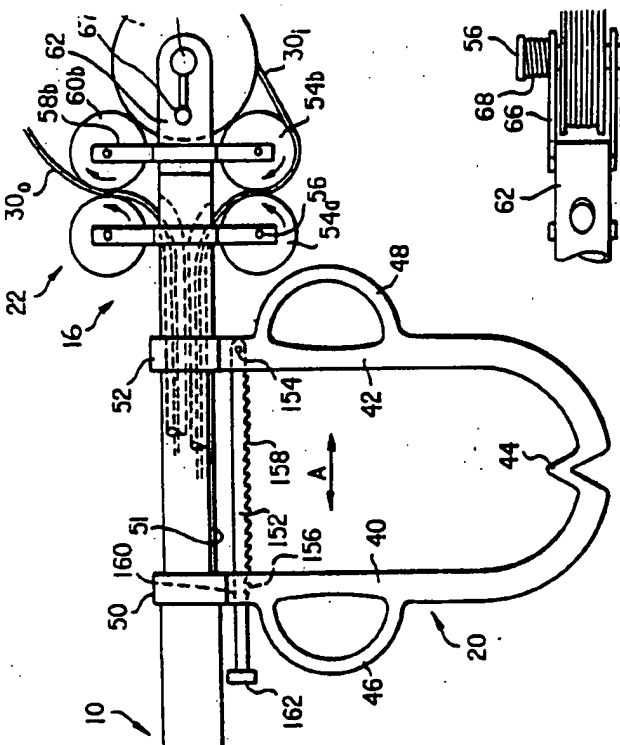

FIG. 1

FIG. 1C

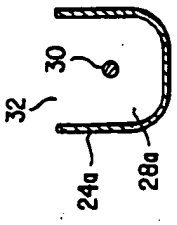

FIG. 5

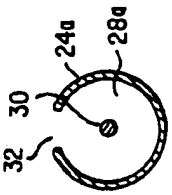

FIG. 4

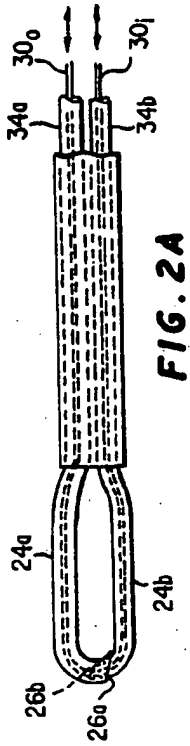

FIG. 2A

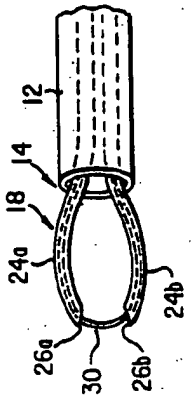

FIG. 2B

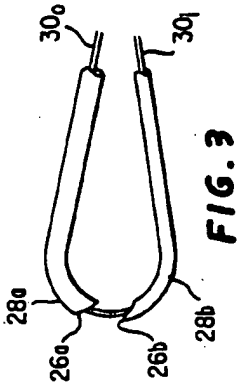

FIG. 3

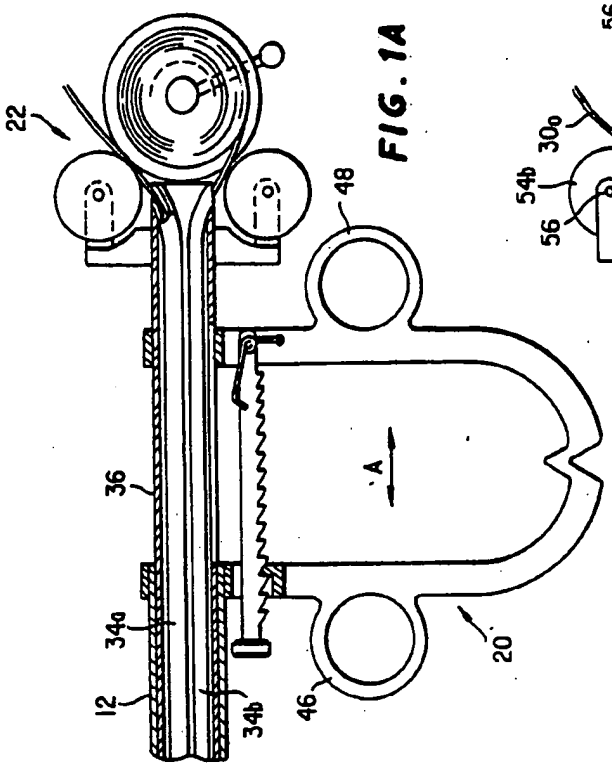

FIG. 1A

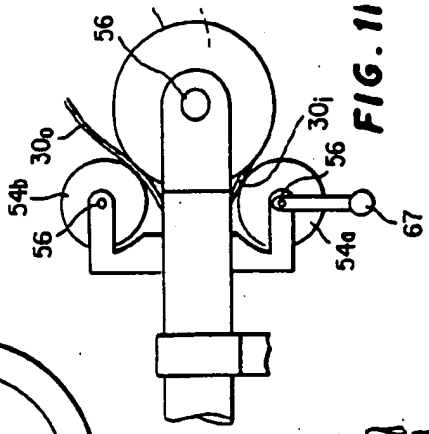

FIG. 11

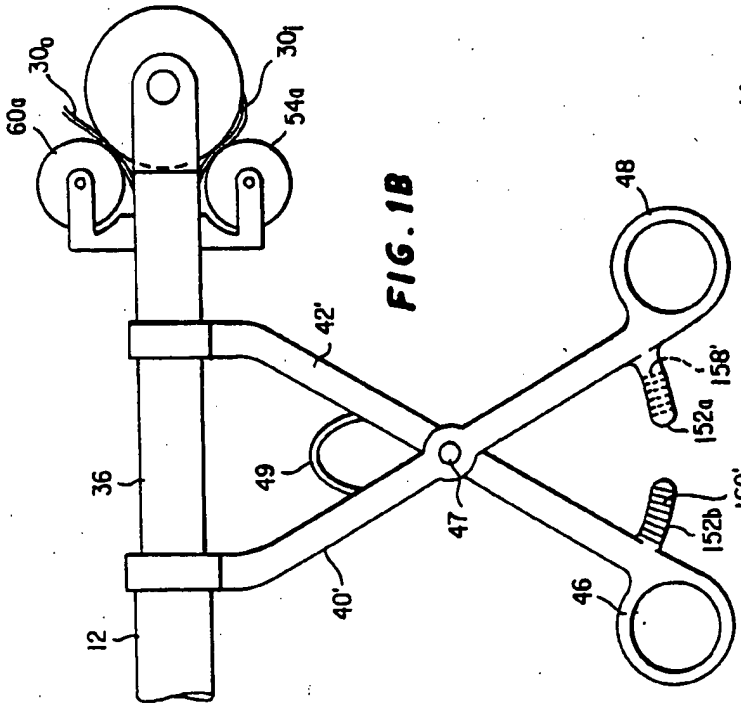

FIG. 1B

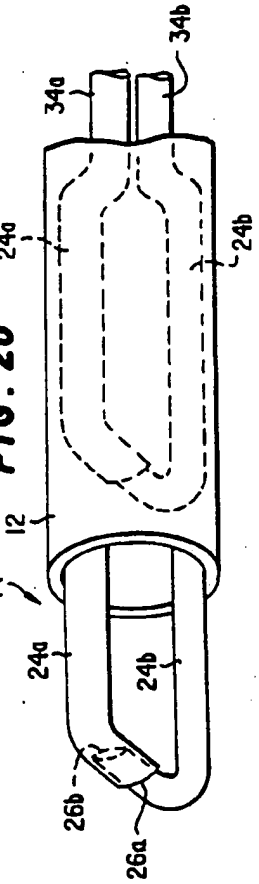

FIG. 20

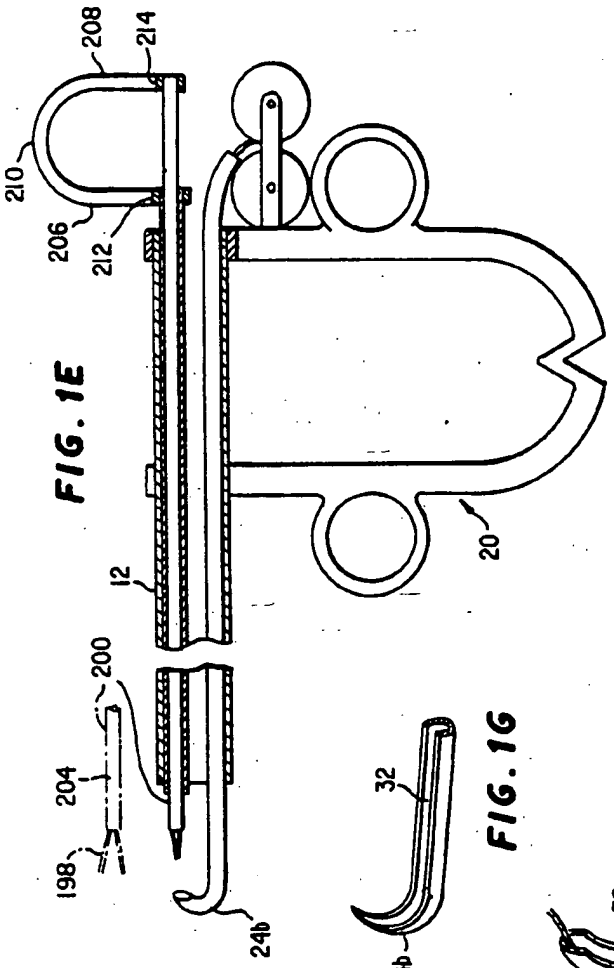

FIG. 1E

FIG. 1G

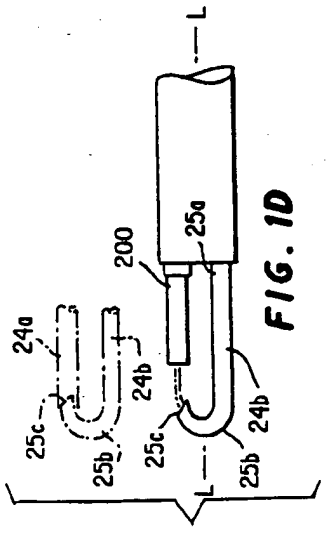

FIG. 1D

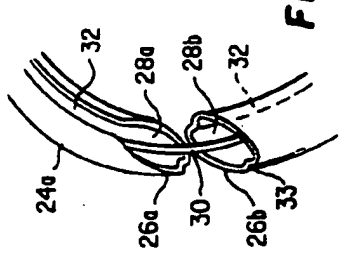

FIG. 10

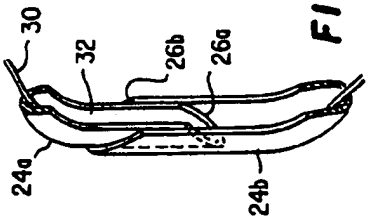

FIG. 9

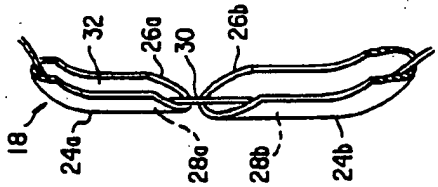

FIG. 8

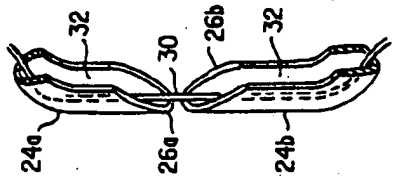

FIG. 7

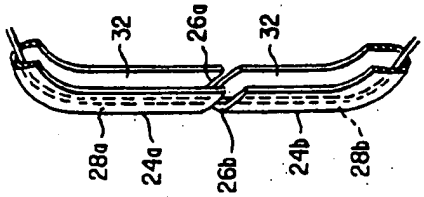

FIG. 6

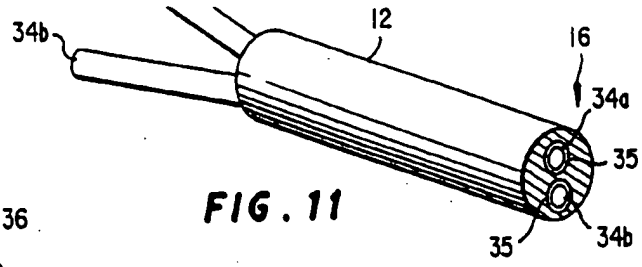

FIG. 11

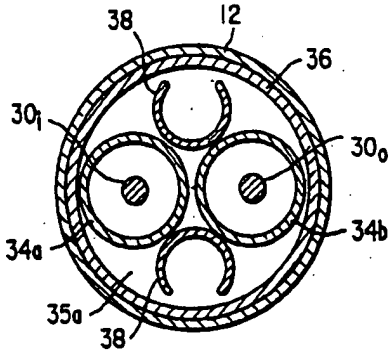

FIG. 12A

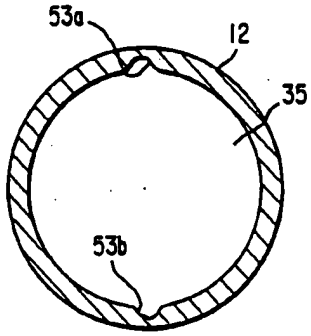

FIG. 12B

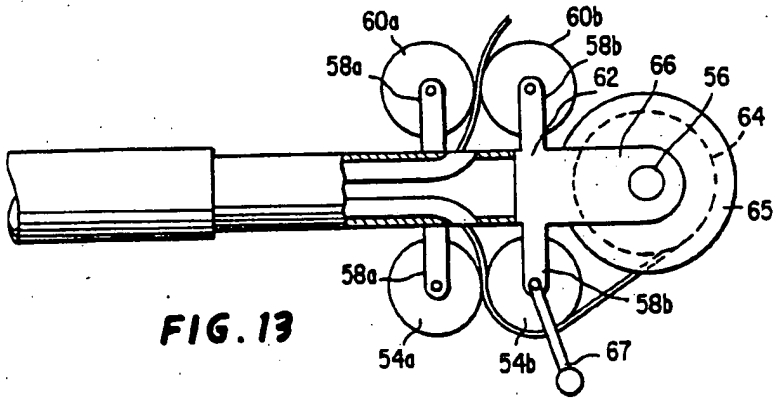

FIG. 13

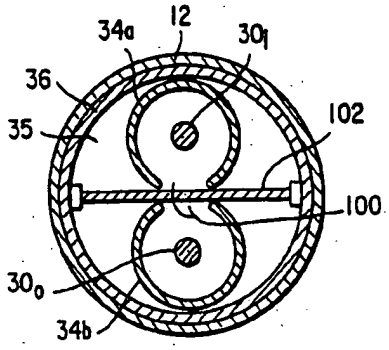

FIG. 16

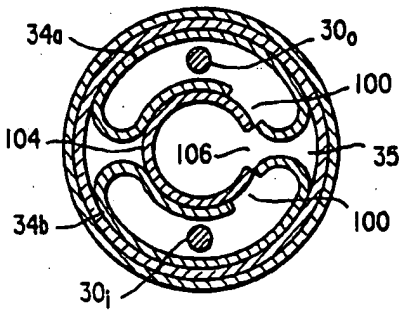

FIG. 17

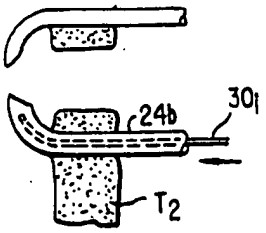

FIG. 14A

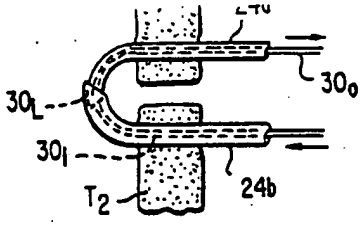

FIG. 14B

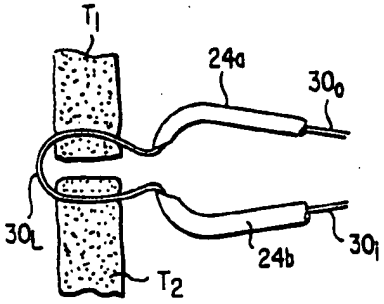

FIG. 14C

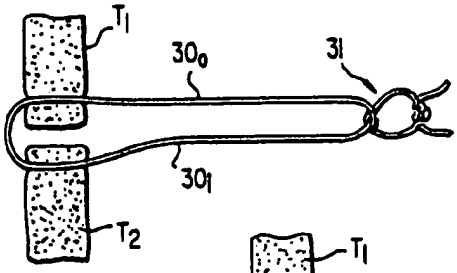

FIG. 14D

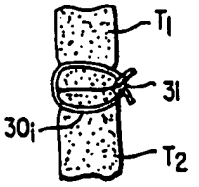

FIG. 14E

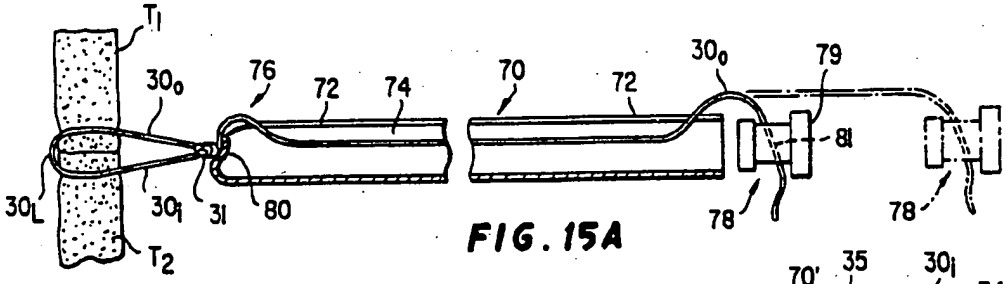

FIG. 15A

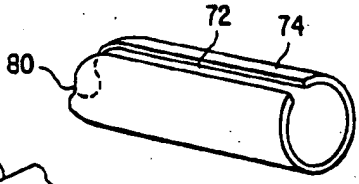

FIG. 15B

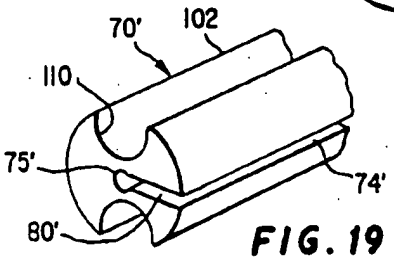

FIG. 19

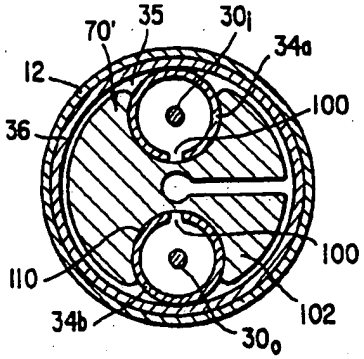

FIG. 18

SURGICAL SUTURE INSTRUMENT WITH REMOTELY CONTROLLABLE SUTURE MATERIAL ADVANCEMENT

BACKGROUND OF THE DISCLOSURE

The invention relates generally to surgical instruments, and particularly to surgical instruments for suturing tissue at a surgical site. More particularly, the invention relates to surgical suturing instruments that are controllable from a position remote from the surgical site to effect tissue suturing at the surgical site.

Suturing of bodily tissue is a time consuming aspect of most surgical procedures, including both open surgery and endoscopic or closed surgery. The term "open" surgery as used herein relates to surgical procedures in which the surgeon gains access to the surgical site by way of a relatively large incision formed in an exterior portion of the patient's body. The terms "endoscopic" or "closed" surgery as used herein relate to surgery in which the surgeon gains access to a surgical site positioned beneath the surface of the patent's body by way of one or more portals through which one or more endoscopic devices can be introduced to view the surgical site. A variety of instruments such as forceps, cutters, applicators and the like can be introduced through the portals to the surgical site. Endoscopic surgery has gained popularity in recent years due to the relatively reduced degree of trauma and incapacitation associated with such procedures and the comparatively faster rates of patient recovery therefrom. Commonly performed endoscopic surgical procedures include arthroscopy, laparoscopy (pelviscopy), gastroentroscopy, and a laryngobronchoscopy.

Prior to the development of the subject suture device, suturing had been accomplished through the use of a sharp, curved metal suture needle having attached to a back end of the needle a length of suture material. The surgeon or a surgical attendant would extend the surgical needle and trailing suture material through the tissue to be joined by the suture, after which the suture material would be tied into a knot and manipulated such that the knot could be advanced to the tissue site and adjusted for tension in order to accommodate the particular type of tissue being sutured and to permit control of approximation, occlusion and attachment of the tissue. However the process of tissue penetration and knotting of the suture material can be time consuming and tedious work, particularly when performed in connection with microsurgery and endoscopic surgery, and can unduly prolong the duration of surgery, and therefore the period in which the patient is under anesthesia. Accordingly, there exists a need for surgical instruments and procedures which greatly simplify the suturing process, render more expedient suturing, and lessen the period during which the patient is under anesthesia.

SUMMARY OF THE INVENTION

The invention provides an apparatus and method which greatly simplifies surgical suturing and thereby expedites surgical procedures. The invention provides an easily manipulable surgical instrument and method in which opposed forcep jaws can be displaced relative to one another from a remotely-controlled position so as to penetrate tissue segments interposed between the forcep jaws. Suture material can be advanced from one jaw to another so as to form a connecting loop of suture material that extends between the tissue segments to be joined. The suture material is advanced in a continuous manner through the opposed forcep jaws so as to extend outwardly at or near the proximal end of the instrument. Following release of the forcep jaws, a knot can be tied in the suture material so as to join the outwardly-extending end thereof with the inlet supply of suture material, and the knot can be advanced toward the tissue segments so as to join together the tissue segments under the appropriate tension. The suture material can be any of a variety of rigid, semi-rigid, bioabsorbable or non-bioabsorbable suture material.

In an alternative aspect of the invention, the forcep jaws can be fixedly positioned relative to one another but arranged so as to provide a pathway through which suture material can be advanced so as to extend from one forcep jaw into and through the opposed forcep jaw and any one or more tissue segments interposed therebetween. Following continuous advancement of suture material through the opposed forcep jaws, a knot is tied in the suture material and advanced toward the tissue segments to be joined and appropriately tensioned to provide a suture.

BRIEF DESCRIPTION OF THE DRAWINGS

Further details of the subject invention will become apparent from a reading of the following detailed description when read in conjunction with the accompanying drawings, in which:

FIG. 1 is a longitudinal side view of a surgical suturing device in accordance with the invention;

FIGS. 1A–1F illustrate details of alternative arrangements for use in the apparatus depicted in FIG. 1;

FIG. 1G is an enlarged view of a portion of the instrument depicted in FIG. 1E.

FIGS. 2A and 2B are views of alternative arrangements of the forcep assembly of FIG. 1;

FIG. 3 is an enlarged view of the forcep assembly of FIG. 1;

FIGS. 4 and 5 are cross-sectional views of a forcep arm;

FIGS. 6–10 are alternative forcep configurations;

FIGS. 11 is a partial sectional view of a portion of the instrument of FIG. 1;

FIGS. 12A and 12B are cross-sectional views of various portions of the instrument of FIG. 1;

FIG. 13 is a detailed side view of a portion of the instrument of FIG. 1;

FIGS. 14A–14D are schematic views illustrating operation of the invention;

FIG. 15A is a side view of a suture knot advancing device that can be used various configurations of the instrument depicted in FIG. 1; and

FIG. 15B is an enlarged view of the distal end of the device depicted in FIG. 15A.

FIGS. 16 and 17 are cross-sectional views of an alternative aspect of a portion of the instrument depicted in FIG. 1.

FIG. 18 is a cross-sectional view of an alternative aspect of the device depicted in FIG. 16; and

FIG. 19 is a perspective view of a distal portion of the device depicted in FIG. 18.

FIG. 20 is a side view of the forcer assembly depicted in FIG. 2A illustrating partial and complete retraction of the forcep within the surgical suture device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to the drawings, wherein like reference characters designate like components throughout the various views, and with particular reference to FIG. there is depicted a suturing instrument 10 for suturing tissue at a surgical site. The suture instrument 10 comprises a tubular member 12 having a distal end 14 and a proximal end 16, a forcep assembly 18 positioned at the distal end 14 of the tube, a handle assembly 20 positioned adjacent to the proximal end of the tube, and suture advancing means 22 coupled to the proximal end of the instrument. As used throughout this disclosure, the distal end generally refers to the left-hand side of a drawing, whereas the proximal end generally refers to the right-hand side of the drawing, unless otherwise specified.

The forcep assembly 18 is comprised of a pair of opposed forcep arms 24*a* and 24*b*, each terminating at its respective distal end at a tip 26*a* and 26*b*. One or both of the forcep arms 24*a*, 24*b* can be arranged so as to be displaceable relative to the distal end 14 of the tubular member 12 to move the distal tips 26*a*, 26*b* between an open position, as illustrated in FIG. 1, and a closed position, as illustrated in FIG. 2A, or the opposed forcep arms can be fixed in position with a separation space therebetween of prescribed dimensions, as illustrated in FIG. 2B. The arms 24*a* and 24*b* of the forcep assembly can have a variety of configurations, such as the outwardly, distally curved configuration illustrated in FIG. the generally planar configuration illustrated in FIG. 2B, or a variety of other configuration as may be desirable in accordance with the tissue type to be sutured, the location of the surgical site, and other considerations.

The forcep arms 24*a* and 24*b* each define a forcep lumen 28*a*, 28*b* through which suture material 30 is extensible in a manner described in greater detail below. The forcep arms 24*a* and 24*b* can be provided with a closed cylindrical configuration, as indicated in FIG. 3, or they can be provided with a generally "C"-shaped or "U"-shaped cross-sectional configuration, as illustrated in connection with forcep arm 24*a* in FIGS. 4 and 5, so as to provide an open channel 32 extending the length of each of the respective forcep arms 24*a* and 24*b*. The channel openings 32 facilitate fluid drainage from the forcep assembly 18 and allow for advancement in a manner described below through the forcep assembly 18 of a suture knot (not depicted) formed in the suture material 30.

With reference to FIGS. 6–10, there is depicted a variety of configurations for approximation of the distal tips 26*a*, 26*b* of the forcep arms 24*a*, 24*b*. For example, FIG. 6 illustrates alignment and positioning of the distal tips 26*a*, 26*b* in close proximity with one another so as to contact or nearly contact one another. The distal tips 26*a* and 26*b* terminate at relatively sharp edges so as to facilitate tissue piercing upon tip approximation. As illustrated in FIG. 6, the tips 26*a*, 26*b* are angled in a complementary fashion to one another such that both forcep tips are angled distally upwardly. FIG. 7 illustrates an alternative tip configuration in which lower distal tip 26*b* is angled distally upwardly, whereas upper distal tip 26*a* is angled distally downwardly. FIGS. 8 and 9 illustrate further alternative configurations for the forcep arms and the distal tips thereof upon displacement of the forcep arms to the closed position. In FIG. 8, forcep arms 24*a* and 24*b* are configured such that arm 24*a* is dimensioned so as to be received within lumen 28*b* of the lower forcep arm 24*b* upon forcep arm closing, as illustrated by the phantom lines in the drawings. Furthermore, the respective distal tips are angled relative to one another in the manner analogous to that illustrated in FIG. 7. FIG. 9 illustrates an angular relationship of distal tips 26*a* and 26*b* analogous to that depicted in FIG. 6, with the exception that the upper forcep arm 24*a* is configured so as to be received within the lumen 28*b* of lower forcep arm 24*b*, as illustrated in phantom. FIG. 10 illustrates a further forced arm configuration, in which one forcep arm, such as forcep arm 24*a*, is dimensioned to be received within the lumen of the other forcep arm, such as lower forcep arm 24*b*. Respective dimensional relationships of the distal tips 26*a* and 26*b* of the respective forcep arms can be reversed such that lower forcep arm 24*b* is received within the lumen 28*a* of upper forcep arm 24*a*, if desired. In either arrangement of forcep arms, the distal tips 26*a* and 26*b* extend distally downwardly. This arrangement minimizes the occurrence of suture snagging or tearing upon removal of the forceps from the suture site incident to knot formation in the manner described below. The distal tips 26*a*, 26*b* of the forcep arms of any of the various forcep configurations as illustrated in FIGS. 6–10 can be provided with a tip configuration as illustrated in FIG. 10, in which the distal edge of the forcep tip is provided with a smooth umbricated or concave slot 33 that extends inwardly toward the forcep arm lumen 28*a*, 28*b*. This arrangement can be provided to further minimize the occurrence of suture material snagging and tearing from engagement with sharp edges of the distal tip that could otherwise occur in the absence of such slots 33.

A further alternative forcep arrangement is illustrated in FIGS. 1D and 1E. In this alternative forcep configuration, one of the forcep arms, such as the lower forcep arm 24*a*, is configured in a generally hook-shaped configuration comprising a generally distally extending leg 25*a*, a curved medially-extending leg 25*b*, and a proximally-extending leg 25*c*. The curved leg 25*b* is arranged such that it extends from one side of the longitudinal axis L of the tubular member 12 to the other side thereof so as to enable tissue segment piercing and joining by the single forcep arm 24*b*. In this manner, suture material can be advanced within lumen 28*b* of the forcep arm 24*b* so as to extend through all tissue segments to be joined before emerging therefrom. The suture material exiting the proximal leg 25*c* of the forcep arm 24*b* can be received by upper forcep arm 24*a*, which can be configured as a fixed or displaceable arm having a lumen 28*a* in the manner described above (FIG. 1), or as a tubular rod 200 carrying a plurality of radially extensible forcep tongues 198 (FIG. 1E) that are selectively extensible and retractable upon manipulation of handle 202 mounted at the proximal end thereof. The rod 200 is arranged as an extensible tubular member received within tubular member 12 and includes a selectively extensible and retractable inner rod 204 having mounted at its distal end the array of forcep tongues. The handle 202 is provided with a generally inverted U-shaped configuration that includes a distal arm 206 coupled to proximal arm 208 by spring arm 210. The free end 212 of handle arm 206 is coupled to the exterior of rod 200, whereas the free end 214 of handle arm 208 is coupled to rod 204 such that, upon urging of handle arms 206, 208 toward one another, rod 200 is

displaced toward the proximal end of the instrument as the inner rod **204** is displaced distally to permit the forcep tongues to extend radially outwardly so as to define an opening for grasping the distal end of suture material emerging from the opposed forcep arm **24***b*. Upon release of handle tension, the inner rod **204** is retracted within outer the rod and the flange tongues **198** grasp firmly against the suture material to secure the suture material therebetween. Once the suture material has been grasped by the forcep tongues **198**, the rod **200** can be withdrawn from tubular member **12** so as to circulate suture material through forcep arm **24***b* and advance the grasped free end of the suture material proximally to permit suture knot tying. Once a suture knot has been tied, the knot can be advanced to the tissue segments joined thereby in the manner described below, as by use of the aforedescribed device **70** (FIG. **15**A).

The forcep arm **24***b* can be configured so as to be defined by a closed sidewall, as shown in FIG. **1**E, or by an open-sided sidewall of generally C-shaped or U-shaped cross-sectional configuration, as shown in FIG. **1**G.

FIG. **11** illustrates details of the tubular member **12** of the instrument **10**. The tubular member **12** is provided with a pair of inner tubular members **34***a* and **34***b* which extend from the proximal end **16** to the distal end **14** of the outer tubular member **12**. The inner tubular members **34***a* and **34***b* can be in the form of tubular channels borred in a tubular member **12** that is solid in cross-section, as indicated by reference numeral **35**, or they can be in the form of discrete tubular members positioned within a cavity **35***a* formed in the outer tubular member **12**, as shown in FIG. **12**A. The inner tubular members **34***a* and **34***b* are preferably arranged in axial alignment with forcep arms **24***a* and **24***b*, respectively, and are in fluid communication with the respective lumens **28***a*, **28***b* thereof so as to provide for the advancement of suture material **30** therethrough. In particular, it is desirable to advance suture material **30** from the proximal end **16** of the outer tubular member **12** through one of the inner tubular members, such as inner tubular member **34***a*, through the lumen **28***a* of the corresponding forcep arm **24***a* so as to extend in a continuous manner into the lumen **28***b* of the opposed forcep arm **24***b* for return passage through the other of the inner tubular members **34***b* proximally in this described configuration. However, it is to be appreciated that the respective directional orientations of suture material advancement can be reversed from that described above such that suture material advances from the proximal end **16** of the tubular member **12** through inner tubular member **34***b* so as to be conveyed through lower forcep arm **24***b*, through upper forcep arm **24***a*, and back through inner tubular member **34***a* for knot tying in the suture material.

In a further preferred arrangement for the outer tubular member **12**, inner tubular members **34***a* and **34***b* are secured in a conventional manner to the inner wall of a middle tubular member **36** concentrically received within outer tubular member **12**. A pair of tubular channel members **38** can be positioned adjacent the inner tubular members **34***a*, **34***b* so as to extend longitudinally through middle tubular member **36**. The tubular channel members **38**, which can be configured as closed-sided tubular channels, or as generally "C"-shaped or open-sided channels as shown, provide for the circulation of fluid to and from the surgical site, as well as for the insertion therethrough of one or more auxiliary surgical instruments such as fiber optic and other imaging, treatment or diagnostic apparatus, and can be permanently or detachably mounted to the middle tubular member **36**. Detachable mounting of the channel members **38** can be advantageous when preparing the surgical instrument **10** for sterilization following use on a patient or when the channel members are arranged to be disposable and replaceable by replacement channel members formed from a suitable material, such as plastic. In this and subsequent drawings, extension of the suture material **30** through the respective inner tubular members **34***a* and **34***b* is directionally oriented such that advancement of the suture material toward the forcep assembly **18** is designated **30***i* (inlet), whereas return of the suture material therefrom is designated as **30***o* (outlet). As noted previously, the respective directional orientations of advancement of the suture material through inner tubular members **34***a* and **34***b* can be reversed from that described herein, if desired.

With reference again to FIG. **1**, the handle assembly **20** includes a distal arm **40** joined to a proximal arm **42** through a spring member **44**. Handling rings **46** and **48** are provided such that ring **46** is mounted to distal arm **40** and ring **48** is mounted to proximal arm **42**. The handling rings **46**, **48** are dimensioned so as to receive one or more fingers of a user so as to facilitate relative displacement of the handle arms **40**, **42** inwardly or outwardly, as indicated by the arrow A, and can be provided with a variety of different configurations, such as half-circular (FIG. **1**) or annular (FIG. **1**A). The shoulder **50** (FIG. **1**) of distal arm **40** extends through slot **51** formed in the outer tubular member **12** to engage the inner tubular members **34***a* and **34***b* either directly or by way of engagement with middle tubular member **36** (FIG. **12**A). The shoulder **52** of proximal handle arm **42** is coupled to the outer tubular member **12** such that movement of the handle arms **40** and **42** toward one another results in proximal displacement of forcep arms **24***a* and **24***b* so as to close the respective tip portions **26***a* and **26***b* toward one another as the forcep arms are retracted within distally extending outer tubular member **12**. The forcep assembly can be arranged so as to be partially or fully retracted within outer tubular member **12**, as shown in solid lines and in phantom, respectively, in FIG. **20**. Slots **53***a*, **53***b* can be formed along the interior surface of the distal portion **14** of the outer tubular member **12**, as shown in FIG. **12**B, to provide a guiding structure along which the proximally-displaced portions of the forcep arms **24***a*, **24***b* can slide incident to closure or approximation to facilitate retraction (and extension) of the forcep assembly relative to the outer tubular member during forcep arm manipulation through the handle assembly **20**. Displacement of the handle arms **40** and **42** away from one another, as would occur upon the release of the compressive force stored in the spring member **44** generated by the movement of the handle arms **40** and **42** toward one another, results in proximal movement of the outer tubular member and simultaneous distal movement of inner tubular members **34***a* and **34***b* (and any surrounding middle tubular member **36** that may be present) so as to release and extend the forcep arms **24***a* and **24***b* to the open position illustrated in FIG. **1**.

The relative position of handle arms **40** and **42** can be fixed by selective engagement of locking mechanism **150** so as to correspondingly fix the relative positions of the opposed forcep arms **24***a* and **24***b*. The locking

mechanism 150 includes an arm or bar 152 pivotably mounted to one of the handle arms such as arm 42, by pivot means such as pivot pin 154, that extends through a slot 156 formed in the other handle arm 40. The lock arm 152 can be configured as a gear rack having a plurality of angled or ratchet-like protrusions 158 formed along a portion of the exterior surface of the arm that are selectively engageable with corresponding, complementary-angled or ratchet-like protrusions 160 formed along one of the sides of the slot 156 upon rotatable manipulation of the lock arm 152 by handle 162 so as to bring the respective arm and slot protrusions 158, 160 into juxtaposition. Locking of the handle arms can be advantageous so as to free the user's hands to operate further components of the instrument, such as the suture material advancing means 22 described below, or to operate other equipment related to the surgical procedure to be used in conjunction with, or independently of, the instrument 10.

In an alternative arrangement, the handle 20 can be configured as a scissor-like handle, as illustrated in FIG. 1B, in which the distal and proximal arms 40' and 42' are pivotably coupled to one another at pivot 47 and are resiliently biased by spring means 49 in a position so as to orient the forcep arms 24*a*, 24*b* coupled thereto in any of the manners described above in a predetermined position. For example, coupling of distal scissor arm 40' to outer tubular member 12 and proximal scissor arm 42' to inner tubular member 34*a*, 34*b* either directly or through middle tubular member 36, as shown, predisposes the forcep arms to maintain in an open (separated) position until the handle arms 40', 42' are urged toward one another against the force exerted by spring means 49. The handle arms 40', 42' can be locked together in a selected position through engagement of mutually engageable locking arms 152*a*, 152*b* and their respective, correspondingly-configured engagement surfaces 158', 160' as described above in connection with the locking arrangement depicted in FIG. 1.

With reference to FIGS. 1 and 13, the suture material advancing assembly 22 positioned at the proximal end 16 of the outer tubular member 12 comprises a pair of inlet guide rollers 54*a*, 54*b* pivotably mounted by pins 56 to support arms 58*a* and 58*b*, respectively. Positioned opposite the inlet guide rollers 54*a* and 54*b* is a pair of outlet guide rollers 60*a* and 60*b* mounted by pins 56 to support arms 58*a* and 58*b*, respectively. The support arms 58*a* and 58*b* are, in turn, are-mounted to a support rod 62 which is coupled at its distal end to the outer tubular member 12 at shoulder 52. The support rod 62 can be disengageably-mounted with respect to the outer tubular member 12 to permit its removal therefrom incident to replacement, cleansing and sterilization of the instrument, as well as to permit for the insertion of various supplemental instruments through the cavity 35 of the outer tubular member. Alternatively, the support rod 62 can be fixedly mounted to the tubular member 12. A supply 64 of suture material 30 mounted within reel assembly 65 is coupled thereby to rod 62 through opposed flanges 66 (FIG. 1C) and pin 56. Manually or automatically-operable provisions for advancing suture material from the supply reel 65 can be provided. In the arrangement depicted in FIG. 1, a hand-operated crank 67 coupled to the supply reel 65 through a conventional spring release assembly, designated generally by reference numeral 68, can be provided to control the advancement of suture material between inlet rollers 54*a* and 54*b*. The spring release assembly 68 can be of the type which provides a spring resistance to rotation of the reel 65 unless the reel 65 is displaced laterally with respect to flanges 66 to prevent inadvertent release of suture material from the reel 65, or can be coupled to an automatically operable device such as a spring motor (not shown) that is wound upon rotation of the handle of a winding device 67 in a predetermined direction. Alternatively, the winding handle 67 and any related winding apparatus can be arranged so as to be operable with respect to one or both of intake rollers 54*a*, 54*b* (FIG. 13) in order to provide for automatic or manual advancement of suture material into an appropriate one of the inner tubular members 34*a*, 34*b*. It is to be appreciated that advancement of suture material in any of the above-described manners advances suture material through one of the inner inlet tubular members, such as 34*b*, through corresponding forcep arm 24*b* so as to extend into and through opposed forcep arm 24*a* and return proximally through inner tubular member 34*a* to emerge between opposed outlet rollers 60*a* and 60*b* for further manipulation, such as future knot tying. Alternative roller arrangements to that depicted in FIG. 1 can be provided for the advancement of suture material. For example, single inlet and outlet rollers 54*a*, 60*a* (FIG. 1F) can be provided in lieu of the multiple roller arrangement of FIG. 1. The spring release and crank assembly can be mounted to the inlet roller 54*a* as shown, or to the reel 65 in the manner described above to control the supply of suture material to the forcep assembly 18 in the manner described above.

Alternative configurations and modes of operation for the suture material advancing means 22 can be substituted for the handle and crank assembly described above. For example, suitable DC-powered or spring-powered motor assemblies can be provided to advance the suture material distally through the forcep arms 24*a* and 24*b* in a continuous manner until disengagement of motor actuation in the case of the DC-motor or uncoupling of the spring motor from the suture supply reel. Such "automated" suture advancing systems may be particularly advantageous in configurations of the suture instrument 10 in which the outer tube 12 thereof is provided with a length of on the order of about 30 cm or longer so as to minimize operator fatigue and expedite the suturing process. Alternatively, the suture material can be manually advanced into the outer tubular member 12 by configuring the supply reel 65 as a thumb-roller in frictional engagement with the inlet roller 54*b* and the outlet roller 60*b* such that rotation of the reel roller 65 directs relative movement of the respective inlet rollers 54*a*, 54*b* so as to draw suture material therebetween from the reel 65 to advance the suture material distally, through the forceps 24*a*, 24*b*, and outwardly therefrom to exit the instrument 10 between outlet rollers 60*a*, 60*b*. Advancement of suture material is terminated upon the user's cessation of operation of the thumb roller 65, thereby providing the user with a high degree of control as to the amount and rate of suture material advancement through the instrument.

FIGS. 14A–14D illustrate schematic form formation of a suture with the instrument. Two or more tissue or organ segments to be sutured, designated T1 and T2 throughout the drawings, are positioned between the open forcep arms 24*a* and 24*b* and are pierced thereby upon closure of the forcep arms, as illustrated in FIG. 14A in the manner described above. Suture material 30*i* is advanced distally toward the tissue T1, T2 through one of the forcep arms (forcep arm 24*b* in the drawings),

through the opposed forcep arm (24a), and returns proximally, as illustrated in FIG. 14B, preferably through the corresponding inner tubular member 34a (FIGS. 11 and 12A). Following extension of the suture material through the tissue segments T1 and T2, the forcep arms are separated from one another and removed from the tissue, leaving a loop 30L of suture material extending between the tissue segments T1 and T2. As the forcep arms 24a, 24b are withdrawn from the tissue segments, suture material can be advanced by way of any one of the foregoing suture advancing arrangements through the instrument and tissue segments in the direction of the arrows (FIG. 14C). Once the instrument has been removed from the suture site, a surgical knot 31 (FIG. 14D) can be tied in the suture material, advanced to the tissue segments, and appropriately tensioned to join the tissue segments together, as shown in FIG. 14E.

A device 70 that is helpful in advancing the suture knot 31 to the tissue segments T1 and T2 is illustrated schematically in FIGS. 15A and B. The knot advancing device comprises an elongated tubular structure 72 having formed therein a longitudinal slot 74 which extends from the distal end 76 to the proximal end 78 of the device. A knob 79 detachably mounted at the proximal end of the device includes means such as an angularly extending slot 81 for receiving the suture material from the groove. A recess 80 formed at the distal end of the device 70 is provided for receiving the knot 31 therein. The device recess 80 is advanced distally against the knot 31, and the outwardly-extending length of suture material 30o is pulled along groove 74 and along slot 74 as the knob 79 is advanced proximally, as indicated in phantom, to advance the suture knot into a desired tensioned engagement with tissue segments T1 and T2 joined by the suture loop 30L.

In an alternative configuration of the instrument 10, as illustrated in FIGS. 16 and 17, the inner tubular members 34a and 34b are each provided with a generally "C"-shaped or "U"-shaped cross-sectional configuration (FIG. 16), or an open-sided crescent-shaped configuration (FIG. 17) so as to provide a longitudinally extending channel 100 extending into the cavity 35 of the outer tubular member. The channels 100 are dimensioned so as to permit passage therethrough of suture material 30o and 30i. The channels 100 can be closed off by suitable obstructing means such as a plate member 102 (FIG. 16) or a rotatable rod 104 having a generally "C" or "U"-shaped cross-section so as to define a lumen 106 for receiving suture material strands 30i and 30o. Removal of plate 102 or rotation of rod 104 such that the rod lumen opening faces the channels 100 permits for displacement of the suture material from the inner tubular members 34a, 34b into the cavity 35 of the outer tubular member, thereby permitting insertion of device 70 into the cavity 35 following suture knot formation so as to advance the suture knot 31 toward the tissue segments T1 and T2 (FIGS. 14A–14D) through the instrument cavity 35. In an alternative arrangement, the plate 102 can be configured as a suture knot advancing device 70' that can be removably mounted within the instrument cavity 35, as illustrated in FIGS. 18 and 19. The device 70' is configured as a generally rod-like structure having a pair of opposed, generally U-shaped recesses 110 formed therein which substantially surround the tubular members 34a and 34b when the device 70' is received within the instrument cavity 35. A longitudinal slot 74' which extends from the distal end of the device 70' to the proximal end of the device is provided to receive the outwardly-extending portion of the suture material following trying of the suture knot. The slot 74' extends from the outer surface of the device 70' medially toward the longitudinal center of the device, where the slot terminates at an enlarged recess 75'. The recess 75' terminates at knot-receiving recess 80' at the distal end of the device. A detachable knob of the type discussed above in connection with FIGS. 15A and 15B can be provided to facilitate suture knot advancement toward the tissue segments to be joined.

In use, the knot advancing device 70' is removed from the suture instrument 10 following advancement of suture material through the tissue segments in the manner described above and illustrated schematically for one aspect of the invention in FIGS. 14A–14E. Once one or more knots have been tied in the suture material, the device 70' is brought alongside the suture material such that the outwardly-extending portion of suture material 30o is positioned within slot 74' and the suture material knot 31 is received within the knot-receiving recess 80' of the device 70'. The device 70' and accompanying knot 31 is re-inserted within the instrument cavity 35 and advanced distally, past the open forcep arms 24a and 24b to an appropriate, tensioned position adjacent the tissue segments to be joined by the suture material.

The foregoing detailed description is illustrious of various embodiments of the suture tying instrument of the subject invention. It will be appreciated from the foregoing description that variations and changes that can be made to the invention as set forth hereinabove and in the accompanying drawings expressly intended to be encompassed by this description and the accompanying claims.

What is claimed is:

1. A surgical suture device, comprising:
   - a cylindrical tubular member defining a cavity extending from a distal end of the tubular member toward a proximal end of the tubular member;
   - a forcep assembly comprising at least two opposed jaw members, at least one of said jaw members being selectively displaceable with respect to said tubular member, each of said jaw members defining a lumen in fluid communication with said tubular member cavity;
   - means for selectively displacing said at least one displaceable jaw member; and
   - means for advancing suture material through said opposed jaw members so as to extend within said tubular member cavity following passage through said jaw members.

2. The device according to claim 1, wherein said tubular member is configured as an outer tubular member defining at least one inner tubular member extending between one of said jaw members and the proximal end of the outer tubular member.

3. The device according to claim 1, wherein said tubular member is configured as an outer tubular member defining at least two inner tubular members, one of said inner tubular members extending between each of said jaw members and the proximal end of the outer tubular member.

4. The device according to claim 3, wherein each of said inner tubular members is provided with a longitudinally-extending channel open toward said outer tubular member cavity.

5. The device according to claim 4, wherein said inner tubular member channels are oriented so as to face one another.

6. The device according to claim 5, further comprising means for closing off at least one of said inner tubular member channels.

7. The device according to claim 6, wherein said inner tubular channel closing off means is selectively removable from the tubular member cavity.

8. The device according to claim 7, further comprising means insertable between said inner tubular member channels for advancing a suture material knot toward said forcep assembly.

9. The device according to claim 8, wherein said suture knot advancing means comprises an elongated member having a recess formed at one end thereof for receiving the suture material knot.

10. The device according to claim 9, wherein said knot advancing means further comprises a slot that extends medially from an outer surface of the member for receiving suture material extending from said suture knot.

11. The device according to claim 10, wherein the elongated member is generally symmetrical along its longitudinal axis.

12. The device according to claim 4, wherein said inner tubular member channels are selectively alignable with one another.

13. The device according to claim 4, wherein each of said inner tubular members is provided with a generally crescent-shaped across-sectional configuration.

14. The device according to claim 4, wherein each of said inner tubular members is provided with generally circular cross section.

15. The device according to claim 3, wherein said inner tubular members are detachably mounted within said other tubular member.

16. The device according to claim 1, wherein each of the opposed jaw members is selectively displaceable relative to said tubular member.

17. The device according to claim 1, wherein each of said jaw members is provided with a sharp-edged distal tip and the opposed jaw members are displaceable relative to one another between an open and a closed position.

18. The device according to claim 17, wherein one of said opposed jaw member distal tips is insertable in the lumen of the distal tip of its opposed jaw member cavity to said jaw member distal tip insertable into said opposed jaw member lumen.

19. The device according to claim 18, wherein said suture advancing means includes means for advancing suture material distally through said tubular member.

20. The device according to claim 17, wherein said opposed distal tips are positionable adjacent one another in close proximity when said jaw members are oriented in the closed position.

21. The device according to claim 20, wherein said jaw member distal tips are angled relative to one another in partially overlapping relationship so as to facilitate tissue piercing upon closing of the jaw members.

22. The device according to claim 21 wherein said opposed jaw member distal tips are angled in opposite directions relative to one another.

23. The device according to claim 21, wherein said opposed jaw member distal tips are angled in substantially similar directions.

24. The device according to claim 1, wherein said jaw member displacing means comprises a handle assembly operable by a user to selectively extend and retract said at least one displaceable jaw member relative to its opposed jaw member.

25. The device according to claim 24, wherein said handle comprises a proximal handle member and a distal handle member, said at least one displaceable jaw member being coupled to one of said handle and the tubular member being coupled to the outer of said handle members.

26. The device according to claim 25, wherein said proximal and distal handle members are coupled to one another by a spring arm.

27. The device according to claim 26, further comprising means for selectively fixing the relative position of said proximal and distal handle members.

28. The device according to claim 25, wherein said proximal and distal handle members are configured as scissor handle members that are pivotably connected to one another.

29. The device according to claim 28, further comprising biasing means for urging said scissor handle members toward a predetermined orientation.

30. The device according to claim 28, further comprising means for selectively fixing the relative position of said scissor handle members.

31. The device according to claim 25, wherein said at least one displaceable jaw member includes means extending through said tubular member cavity for coupling with said respective handle member to effect displacement of the displaceable jaw member.

32. The device according to claim 30, wherein both of said jaw members are selectively displaceable, said inner tubular members being coupled to its respective handle member to effect jaw member displacement upon manipulation of said handle members relative to one another.

33. The device according to claim 31, wherein said means extending through said tubular member cavity comprises an inner tubular member through which suture material is advanceable to said lumen of said at least one displaceable jaw member.

34. The device according to claim 33, wherein said proximal handle member is coupled to said inner tubular member and said distal handle member is coupled to said outer tubular member.

35. The device according to claim 33, wherein said inner tubular member is telescopically extensible within said outer tubular member.

36. The device according to claim 33, further comprising a second inner tubular member extending between the lumen of the other of said opposed jaw members through which suture material is advanceable.

37. The device according to claim 1, wherein said suture material advancing means is detachably mounted to the proximal end of the tubular member.

38. The device according to claim 1, wherein said suture material advancing means comprises means for advancing suture material through the tubular member cavity to one of said forcep jaw members.

39. The device according to claim 38, wherein said suture material advancing means comprises a reel assembly through which suture material can be passed that is selectively operable to advance suture material into said tubular member cavity.

40. The device according to claim 39, further comprising self-powered means for operating said reel assembly.

41. The device according to claim 39, wherein said reel assembly comprises a suture supply reel and at least one pair of opposed roller wheels cooperable with said supply reel to advance suture material through the suture device.

42. The device according to claim 1, wherein at least one of the opposed jaw members is provided with a longitudinally extending slot that extends into said lumen.

43. The device according to claim 1, wherein at least one of said opposed jaw members is provided with an umbricated, concave recess formed at the distal end of the respective jaw member.

44. The device according to claim 1, wherein the device is configured as a reusable instrument that is disassembleable to facilitate instrument cleaning and sterilization.

45. The device according to claim 1, wherein said forcep assembly is selectively retractable within said tubular member.

46. A method for suturing tissue at a surgical site, comprising the steps of:

positioning a suturing instrument adjacent the tissue to be sutured, the suturing instrument having at least two opposed forcep jaw members, at least one of the jaw members being displaceable relative to an instrument body and being selectively operable to move between a forcep open position and a forcep closed position, each of the opposed jaw members defining a lumen extending therethrough;

interposing the tissue to be sutured between the opposed jaw members and urging the displaceable jaw member toward its opposed jaw member to the closed position such that at least one of the jaw members penetrates the tissue to be sutured;

advancing suture material through the opposed jaw members so as to extend through the tissue to be sutured;

urging opposed jaw members of said forceps to said open position;

tying a knot in the suture material; and advancing the suture knot toward the tissue to be sutured.

47. The method according to claim 46, further comprising the step of advancing the suture knot through the instrument body to the tissue to be sutured.

48. The method according to claim 46, further comprising the step of inserting a distal tip of one of the jaw members into the lumen of the other of the opposed jaw members.

49. The method according to claim 48, further comprising the step of advancing the suture material through the lumen of the inserted jaw member and into the lumen of the opposed jaw member.

50. The method according to claim 46, further comprising the step of actuating suture self-advancing means to advance suture material through the opposed jaw members.

51. The method according to claim 42, wherein the suturing instrument is removed from the tissue to be sutured prior to trying of the suture knot.

52. The method according to claim 46, wherein the suture knot is tied prior to removal of the suturing instrument.

53. A device for advancing a knot formed in suture material toward tissue to be sutured, the device comprising an elongated member and a detachable end cap having means for receiving suture material, said elongated member having a knot-receiving recess formed at one end thereof and a longitudinally-extending slot which extends medially from an outer surface of the elongated member.

54. The device according to claim 53, wherein said slot extends from said knot-receiving recess.

55. The device according to claim 54, wherein the device is generally symmetrical about its longitudinal axis.

* * * * *

US005281238A

United States Patent [19]

Chin et al.

[11] Patent Number: 5,281,238

[45] Date of Patent: Jan. 25, 1994

[54] **ENDOSCOPIC LIGATION INSTRUMENT**

[76] Inventors: **Albert K. Chin**, 2021 Newell Rd., Palo Alto, Calif. 94303; **Frank T. Watkins**, 440 Santa Rita Ave., Menlo Park, Calif. 94025

[21] Appl. No.: **25,912**

[22] Filed: **Mar. 3, 1993**

Related U.S. Application Data

[63] Continuation of Ser. No. 796,722, Nov. 22, 1991, abandoned.

[51] **Int. Cl.**[5] **A61B 17/00**

[52] **U.S. Cl.** **606/148**; 606/139; 606/113

[58] **Field of Search** 606/103, 139, 144, 148, 606/110–113, 228, 233; 206/363

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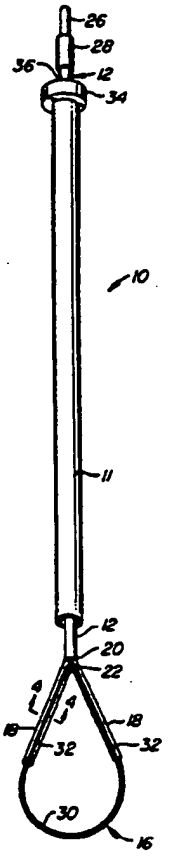
Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Jeffrey A. Schmidt
Attorney, Agent, or Firm—Heller, Ehrman, White & McAuliffe

[57] **ABSTRACT**

An improved endoscopic ligature provided with a loop support means for stabilizing the shape, position and orientation of a suture loop. The stabilized loop is impervious to surface tension forces created by body fluids and will not close on itself or stick to moist surfaces. When the loop is cinched closed it dislodges from the support. The loop support is made of a flexible material with shape memory and has an unstressed width greater than that of the trocar cannula. The loop support is collapsible to allow the instrument to be inserted and withdrawn through the cannula.

21 Claims, 3 Drawing Sheets



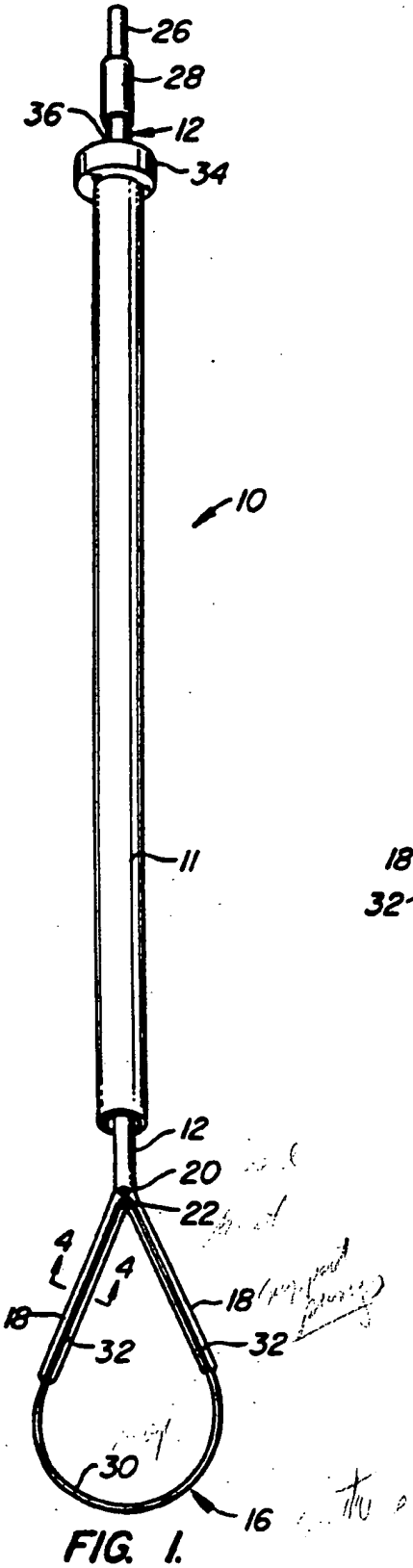


FIG. 1.

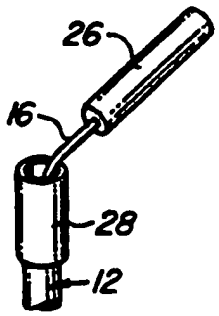


FIG. 2.

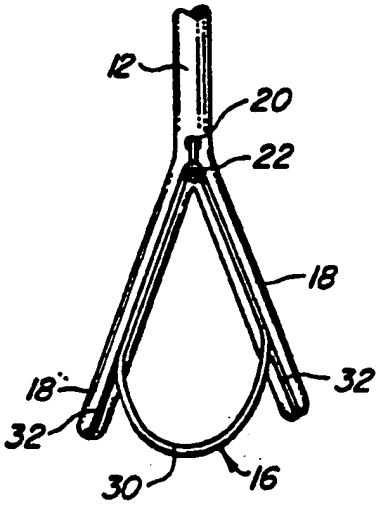
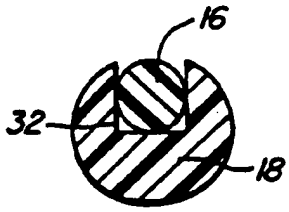


FIG. 3.



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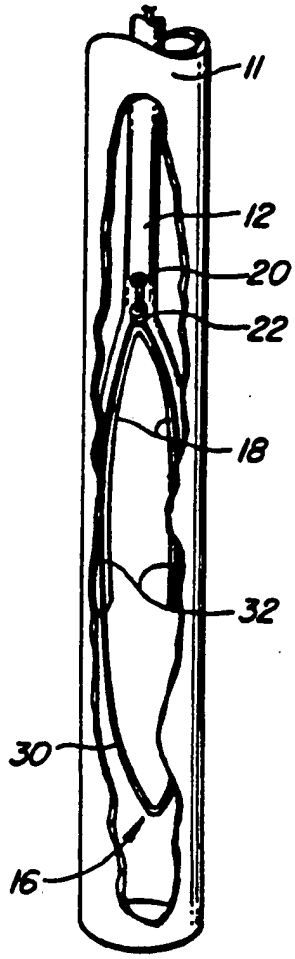

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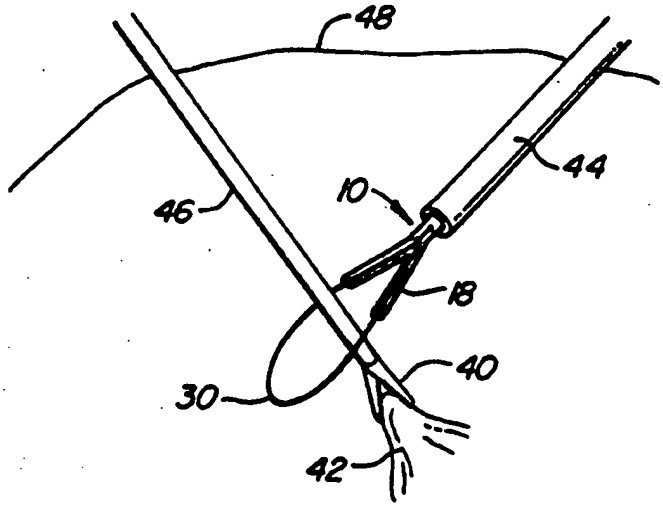

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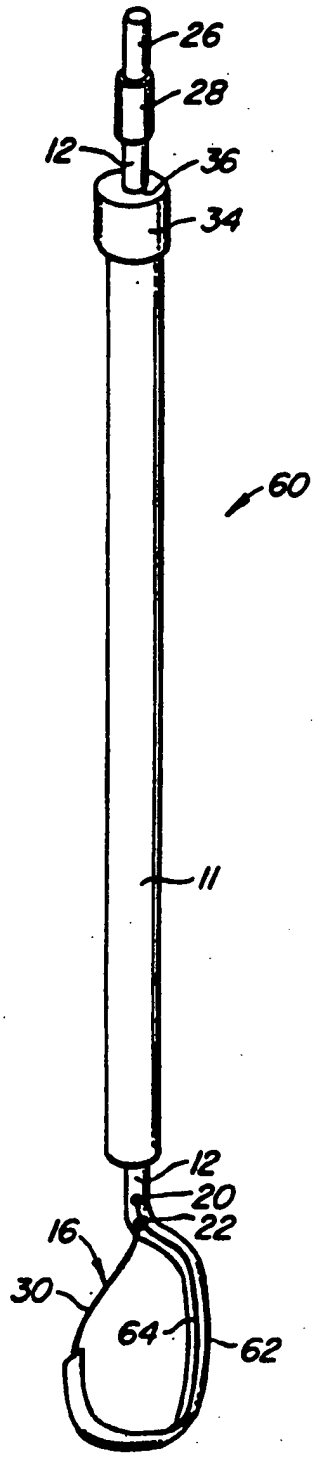

FIG. 7.

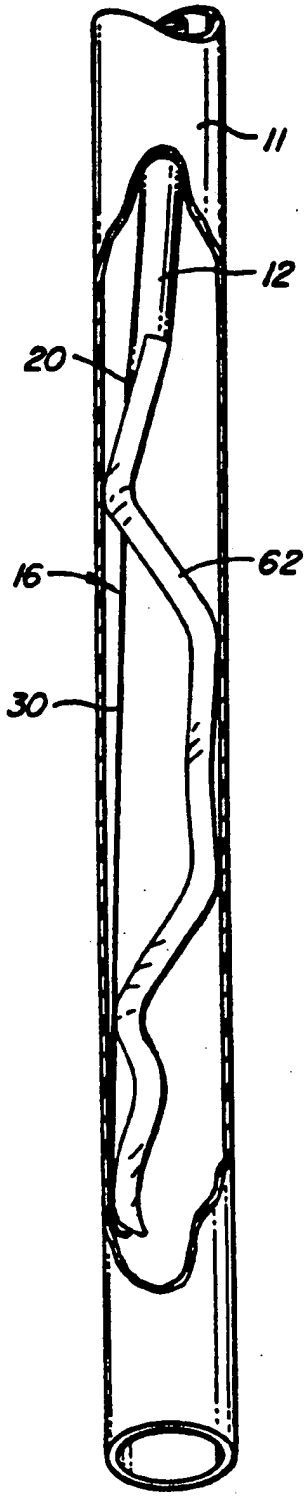

FIG. 8.

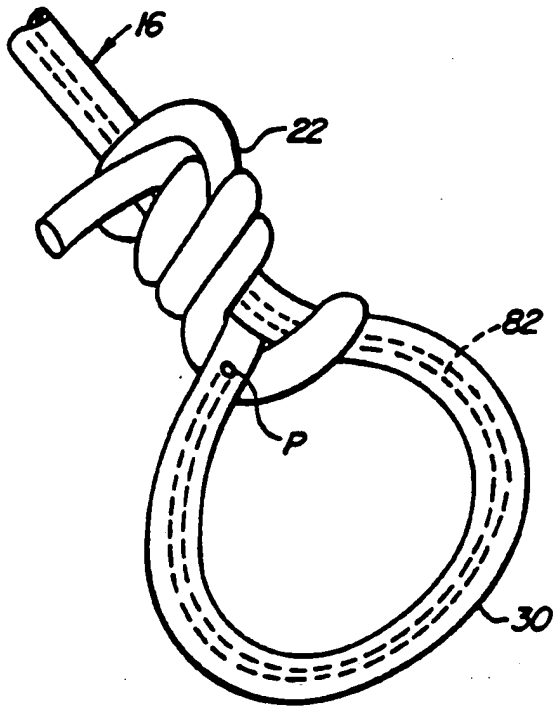

FIG. 9.

ENDOSCOPIC LIGATION INSTRUMENT

This is a continuation of application Ser. No. 07/796,722 filed Nov. 22, 1991, now abandoned.

FIELD OF THE INVENTION

This invention relates to surgical instruments, and in particular endoscopic surgical instruments. Specifically, this invention relates to endoscopic suturing and ligating instruments.

BACKGROUND OF THE INVENTION

The last decade has seen dramatic advances in the field of endoscopic instrumentation, and the application of endoscopic techniques to a growing number of surgical procedures. The benefits—reduced pain and discomfort, shortened recovery time and better cosmetic results—insure that endoscopic surgery will continue to be a rapidly developing and widely applied technique.

Endoscopic surgery is performed with elongated instruments inserted through small holes in the skin, and is viewed through a video monitor. Therefore, such operations require more mental and physical dexterity than corresponding traditional surgical techniques. Because of these additional difficulties it is important to provide surgical tools that are as trouble free and easy to use as possible.

In endoscopic suturing, the knot must be secure and should be as small as possible to prevent tissue reaction. Stress to the suture weakens its strength and should be minimized. Any crimping or crushing of the suture, or any "sawing" between strands during the knot tying process is to be avoided. If the suture must pass through tissue the knot tying can be done extracorporeally or intracorporeally. If ligation is required a slipknot can be tied in the suture beforehand. Ligation is clearly the simpler suturing technique and therefore the method of choice when there is an option. Endoscopic ligatures are used to ligate vessels and tissue pedicles and to close the openings of cystic structures to prevent spillage contamination.

The state of the present technology in endoscopic ligating instruments is represented by the ENDOLOOP ™ manufactured by Ethicon, a Johnson & Johnson Company, and the Surgitie ™ Ligating Loop manufactured by Auto Suture Company, a division of United States Surgical Corporation. These endoscopic ligating instruments have an elongated bored staff with a suture threaded therethrough, the suture forming a loop at the intracorporeal end of the staff. The trocar is provided with a seal mechanism which can form an air-tight seal with the instrument upon insertion of the instrument into the cannula of the trocar. The segment of the staff extending past the seal remains outside the body during surgery and is used as a handle to position the loop. At the extracorporeal end of the staff the suture is connected to a short pull rod that is bonded to the staff. The bond is easily broken by a manual force. The loop is closed by pulling the rod away from the staff.

The instrument is used by placing the loop next to a tissue pedicle or vessel, gripping the tissue with a grasping tool, pulling the grasped tissue through the loop and tightening the loop by separating the pull rod from the staff and pulling it away from the staff.

A drawback of these instruments is that the flexibility of the suture necessary for ligature purposes makes the position and configuration of the loop susceptible to surface tension forces exerted by body fluids. In particular, the surface tension can cause a suture to collapse on itself, closing the loop. It is then difficult to reopen the loop with endoscopic tools, and such manipulations present the risk of inadvertently stressing the suture. Also a wetted suture will tend to adhere to wet surfaces, making it difficult to position the loop in close proximity to tissue. This problem is compounded by the fact that when the suture is wetted, the moisture softens the material. Gut suture is somewhat more impervious than braided Nylon or silk to this softening problem.

SUMMARY AND OBJECTS OF THE INVENTION

The present invention is directed to an improved endoscopic ligature which solves the above-mentioned problems and provides other advantages. The ligature of the present invention has a loop support means which can open the suture loop to a width greater than the width of the cannula, and can be contracted to a width less than the diameter of the cannula for insertion and extraction. The loop support prevents the loop from collapsing due to surface tension forces, and aids in the positioning and orientation of the loop by stiffening the loop so it will not stick to wet surfaces. Upon tightening the loop, the suture disengages from the support.

Therefore, an object of the present invention is to provide an endoscopic ligature with a suture loop that is impervious to surface tension forces induced by body fluids. In particular it is an object of the invention to provide a suture ligature which is easy to position and orient and will not inadvertently collapse on itself. Further objects and advantages of this invention will become apparent upon review of the following specification and claims.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 shows the endoscopic ligature of the present invention with the suture loop retained by the loop support prongs and the pull rod engaged to the staff.

FIG. 2 is an enlarged fragmentary view of the pull rod separated from the retaining tubing and staff.

FIG. 3 is an enlarged fragmentary view of the suture loop partially disengaged from the support prongs.

FIG. 4 is a cross sectional view of a support prong with the suture engaged in the retaining groove.

FIG. 5 shows the ligature with the suture loop and support prongs retracted into the sheath.

FIG. 6 depicts the ligature being used to ligate a tissue.

FIG. 7 displays another embodiment of the present invention where the suture loop is retained by a curved armature.

FIG. 8 displays the ligature of the second embodiment with the armature retracted into the sheath.

FIG. 9 is a view of the suture loop of an embodiment where the suture is supported by an internal wire.

DETAILED DESCRIPTION OF THE INVENTION

As shown in FIG. 1, the endoscopic ligature tool **10** of the present invention is comprised of a gut suture **16** which extends through a bore **20** in an elongated staff **12**. The staff has a length of approximately 9", and a width of approximately $\frac{1}{8}$. A loop **30** in the suture **16** at the intracorporeal end of the staff **12** is secured with a sliding knot **22**. The aperature of the bore **20** at the

intracorporeal end has a diameter greater than the diameter of the suture 16 but smaller than the width of the knot 22 so that the know 22 cannot enter the bore 20. Two flexible support prongs 18 protrude from the intracorporeal end of the staff 12, deviating from the longitudinal axis of the staff 12 with an angle of approximately 20 degrees. The prongs 18 have a length of approximately 1.5". Each prong 18 has a groove 32 along the length of the prong 18 with a width and depth suitable for a dislodgable friction fit with the suture 16 as shown in FIGS. 1 and 3, and in cross-section in FIG. 4. In another preferred embodiment (not shown) the width of the groove 32 near the opening is narrower than the width of the suture 16, so that the groove 32 distorts as the suture 16 is dislodged. In the preferred embodiment the staff 12 and support prongs 18 are made of plastic, e.g. polyvinyl chloride.

The extracorporeal end of the suture 16 is attached to an end of a pull rod 26. The pull rod 26 has a diameter approximately equal to that of the staff 12. The pull rod 26 is removably secured to the end of the staff 12 by a piece of elastomeric retaining tubing 28, preferably composed of polyolefin material. The tubing 28 fits snugly over a short length of the extracorporeal end of the staff 12 and a short length of the pull rod 26 at the end attached to the suture 16. A small manual force produces the separation of the pull rod 26 from the staff 12 as shown in FIG. 2.

Disengaging the pull rod 26 and pulling it 26 away from the staff 12 pulls the suture 16 through the staff 12. When the knot 22 abuts the aperature of the bore 20 the suture loop 30 begins to pass through the knot 22, reducing the size of the loop 30. When the diameter of the loop 30 is approximately equal to the distance between the ends of the support prongs 18 the suture 16 begins to disengage from the grooves 32 as shown in FIG. 3.

As shown in FIG. 1, the majority of the length of the staff 12 is surrounded by a substantially cylindrical sheath 11. Preferably, the sheath 11 is made of a plastic such as polyvinyl chloride, though other types of materials may be used. The sheath 11 has a diameter less than that of the cannula 44 of the trocar (depicted in FIG. 6 and discussed below). The extracorporeal end of the sheath 11 has a rubber cap 34. The staff 12 passes through an aperture 36 in the rubber cap 34 with a diameter slightly less than that of the staff 12. The contact between the staff 12 and the aperture 36 provides an air-tight seal while still allowing the position of the staff 12 in relation of the sheath 11 to be longitudinally adjusted. The sheath 11 can be engaged by the seal mechanism of the trocar (not shown) to prevent intracorporeal gases and fluids from escaping through the cannula 44 during surgery.

Retracting the intracorporeal end of the staff 12 into the sheath 11 forces the support prongs 18 to bend towards the longitudinal axis of the staff 12, as shown in FIG. 5. Because the cannula 44 has a diameter approximately equal to that of the sheath 11, the loop support prongs 18 must be retracted before the intracorporeal end of the ligature 10 can pass through the cannula 44.

Ligation with the present invention is straightforward and free of loop positioning and orientation problems. Access to the surgical region is obtained by puncturing the skin 48 (see FIG. 6) and other selected intervening tissues with a trocar. Preferably the sharp puncturing tip (not shown) of the trocar retracts into the trocar cannula 44 and 46 after puncturing the selected tissues to avoid damage to other tissues, vessels and organs. The cannula 44 or 46 is left in place during surgery to provide a conduit for endoscopic surgical instruments to the surgical region.

Initially segments of the loop 30 are retained by the grooves 32 in the support prong 18. The ligature 10, with the loop 30 and support prongs 18 retracted into the sheath 11 as shown in FIG. 5, is inserted into the cannula 44 of the trocar. The seal mechanism (not shown) of the trocar is then engaged to the sheath 11 to provide an air-tight seal between the internal surgical cavity and the outside. The loop 30 and support prongs 18 are then forced out of the sheath 11 by pushing the staff 12 a short distance through the aperture 36 in the rubber cap 34. The support prongs 18 have shape memory and outside the sheath 11 they spread apart, opening the loop 30 as shown in FIG. 6.

In FIG. 6 a grasping tool 40 which has been inserted into the body through a second cannula 46 which penetrates the skin 48 of the patient. The grasping tool 40 passes through the loop 30 and has grasped a body tissue 42. Because the support prongs 18 retain the loop 30 in an open configuration and maintain the orientation of the loop 30, the loop 30 is impervious to surface tension forces from body fluids. Therefore, the surgeon need not try to prevent the loop 30 of the endoscopic ligature 10 from coming into contact with moisture while positioning the loop 30 or performing other manipulations.

Once the tissue 42 is drawn through the loop 30 the loop 30 is cinched closed by separating the pull rod 26 from the staff 12 and pulling. This draws the knot 22 against the aperature of the bore 20 at the intracorporeal end of the staff 12, and thereafter causes the suture 16 material in the loop 30 to be drawn through the knot 22. When the width of the loop 30 becomes smaller than the distance between the ends of the support prongs 18 the suture 16 begins to dislodge from the support grooves 32. When the loop 30 has ligated the tissue 42 the remainder of the suture 16 still within the groove 32 can be easily dislodged by pulling the end of the staff 12 away from the ligated tissue 42 or pulling the suture 16 away from the support prongs 18 with the grasping tool 40. The suture 16 is cut approximately ¼" from the knot 22. The tool 10 can then be withdrawn through the cannula 44 after retracting the support prongs 18 into the sheath 11 by pulling the staff 12 through the aperture 36 in the extracorporeal direction.

Another embodiment 60 of the present invention is depicted in FIG. 7. In this embodiment 60 the suture loop support means is a curved armature 62 extending from the extracorporeal end of the staff 12. The suture 16 passes through a bore 20 which extends through the staff 12 from the extracorporeal end of the staff 12 to just before the armature 62. A slip knot 22 which closes the loop 30 at the intracorporeal end of the suture 16 has a width greater than the width of the bore 20 at its intracorporeal end. The suture loop 30 is fastened to the armature 62 by a friction fit in a retaining groove 64 along the interior surface of the armature. The components at the extra corporeal end of this embodiment 60 are the same as the components of the first embodiment 10 with the same interrelations, and the same reference numerals are used. The width of the armature 62 is greater than the width of the sheath 11 or the staff 12. The armature 62 is flexible so as to allow it 62 to be retracted into the sheath 11 as shown in FIG. 8 by pulling the staff 12 through the aperture 36 in the rubber cap 34 in the extracorporeal direction. In the preferred

embodiment the staff 12 and armature 62 are made of plastic, e.g. polyvinyl chloride.

The steps followed in the use of this ligature 60 are the same as for the first embodiment 10, and the reference numerals associated with the cannula 44, the grasping tool 40 and the ligated tissue 42 depicted in FIG. 6 are retained in this discussion. With the armature 62 retracted into the sheath 11 as shown in FIG. 8, the ligature 60 is inserted through the cannula 44 of the trocar into the body of the patient. The seal mechanism of the trocar (not shown) engages the sheath 11 to provide an air-tight seal between the intracorporeal surgical cavity and the outside. Pushing the staff 12 through the aperture 36 in the intracorporeal direction pushes the armature 62 out of the sheath 11. Once free of the sheath 11, the armature 62 returns to the hook shape shown in FIG. 7 and the loop 30 is open and ready for ligation. Once a pedicle or vessel 42 is drawn through the loop 30 with a grasping tool 40, the loop 30 is cinched closed by separating the pull rod 26 from the staff 12 and pulling. A segment of the suture 16 which remains lodged in the retaining groove 64 can be dislodged by either moving the staff 12 away from the ligated tissue 42 or pulling the suture 16 out of the groove 64 using the grasping tool 40. The suture 16 should be severed approximately ¼" from the ligation knot 22. Before withdrawal of the ligation instrument 60 through the cannula 44, the armature 62 must again be retracted into the sheath 11.

FIG. 9 shows the intracorporeal end of a third embodiment 80 of the present invention. Components of this embodiment 80 which are the same as the components of the first embodiment 10 and have the same interrelations are referred to by the same reference numerals. In this embodiment 80 the gut suture 16 is supported by a thin support wire 82 (dotted lines) which runs through a bore in the middle of the suture 16. The wire 82 extends from the extracorporeal end of the suture 16 through the loop 30 to a point P just before the knot 22. The wire 82 may be made of spring steel, nitinol or some other material with shape memory. The wire 82 must have sufficient strength to make the suture loop 30 impervious to surface tension effects while still having sufficient flexibility to allow the suture 16 to be cinched closed and to be retracted into the sheath 11 for insertion of the instrument 80 through the cannula 44 of the trocar. The wire 82 is implantable (biologically unreactive) and can be left inside the patient.

When the pedicle or vessel 42 has been drawn through the loop 30 the suture 16 is cinched closed by dislodging the pull rod 26 from the rubber tubing 28 friction fitted to the end of the staff 12 and pulling the rod 26 in the extracorporeal direction. The suture 16 and support wire 82 are then severed approximately ¼' from the knot 22 once the tissue 42 has been ligated. Because the suture 16 which remains attached to the instrument 80 is essentially linear, the instrument 80 is easily withdrawn through the cannula 44 once ligation is completed. When the gut suture 16 eventually dissolves the ligation ceases since the support wire 82 did not extend around the entirety of the loop 30.

From the foregoing description it can therefore be seen that the present invention provides an improved endoscopic ligature which is easy to use and free of difficulties caused by surface tension forces acting on the suture loop. The suture loop of the present invention will not collapse on itself or stick to moist surfaces. Although the specifics of the preferred embodiments have been described in detail for clarity and understanding many other variations are possible. For instance, the ligature of the first embodiment could have the suture loop removably attached only to the ends of the support prongs or the pull rod may be removably fastened to the staff in a different manner; the suture in the second embodiment may be removably retained to the armature with a weak adhesive rather than a retaining groove; or the support wire in the third embodiment may be removed from the loop before cinching. The scope of the present invention should not be determined by the details of the specification but rather by the following claims.

What is claimed is:

1. An instrument for ligation through an endoscopic trocar cannula comprising:

an elongated suture support having an intracorporeal end, and extracorporeal end and a first longitudinal axis;

a suture having an intracorporeal end and an extracorporeal end, said suture extending along and supported by said elongated suture support, said suture having a cinchable loop at the intracorporeal end thereof;

a first adjustable elongated loop support mounted at the intracorporeal end of said elongated suture support, said first loop support having a second central longitudinal axis, said first loop support having a first elongated retaining groove with a third central longitudinal axis, a substantial portion of said loop being removably engageable in said first retaining groove, whereby said first loop support controls and stabilizes said loop when engaged therewith; and

control means located at the extracorporeal end of said elongated suture support for selectively moving said first loop support between a first state and a second state, said second longitudinal axis being more closely aligned with said first longitudinal axis in said first state than in said second state, said third longitudinal axis paralleling said second longitudinal axis in said second state, and said second longitudinal axis being noncolinear with said first longitudinal axis in said second state.

2. The instrument of claim 1 further comprising a second adjustable elongated loop support mounted at the intracorporeal end of said elongated suture support, said second loop support having a fourth central longitudinal axis, said second loop support having a second elongated retaining groove with a fifth longitudinal axis, a substantial portion of said loop being removably engageable in said second retaining groove, whereby said second loop support controls and stabilizes said loop when engaged therewith.

3. The instrument of claim 2 wherein said control means selectively moves said second loop support between a third state and a fourth state, said fourth longitudinal axis being more closely aligned with said first longitudinal axis in said third state than in said fourth state, said fifth longitudinal axis paralleling said fourth longitudinal axis in said fourth state, and said fifth longitudinal axis being noncolinear with said first longitudinal axis in said fourth state.

4. The instrument of claim 3 wherein said first and second loop supports are substantially linear.

5. The instrument of claim 2 wherein said first and second loop supports are substantially nonlinear.

6. The instrument of claim 2 wherein said first and second retaining grooves are configured to frictionally retain said loop.

7. The instrument of claim 2 wherein said loop disengages from first and second loop supports when cinched.

8. The instrument of claim 1 wherein said first loop support is substantially linear.

9. The instrument of claim 1 wherein said first loop support is substantially nonlinear.

10. The instrument of claim 1 wherein said suture support is substantially tubular forming a bore, said bore housing a portion of said suture in a sliding relationship.

11. The instrument of claim 1 wherein said first retaining groove is configured to frictionally retain said loop.

12. An instrument for ligation through an endoscopic trocar cannula comprising:

an elongated suture support having an intracorporeal end, an extracorporeal end and a first longitudinal axis;

a suture having an intracorporeal end and an extracorporeal end, said suture extending along and supported by said elongated suture support, said suture having a cinchable loop at said intracorporeal end thereof, a first point on said loop being removably engageable near said intracorporeal end of said suture support;

a first adjustable elongated loop support prong having a second longitudinal axis, a first distal end, and a first proximal end, and being mounted near said first proximal end to said intracorporeal end of said suture support, said loop being removably engageable to said first support prong at a second point near said first distal end thereof and a third point between said first distal and proximal ends thereof, whereby said first support prong controls and stabilizes said loop when engaged therewith; and

control means located at said extracorporeal end of said suture support for selectively moving said first support prong between a first state and a second state, said second longitudinal axis being more closely aligned with said first longitudinal axis in said first state than in said second state, and said second longitudinal axis being noncolinear with said first longitudinal axis in said second state.

13. The instrument of claim 12 wherein said loop is removably engageable to said first support prong at a fourth point on said first support between said second and third points.

14. The instrument of claim 12 further comprising a second adjustable elongated loop support prong having a third longitudinal axis, a second distal end, and a second proximal end, and being mounted near said second proximal end to said intracorporeal end of said suture support, said loop being removably engageable to said second support prong at a fourth point near said second distal end thereof and a third point between said second distal and proximal ends thereof, whereby said second support prong controls and stabilizes said loop when engaged therewith.

15. The instrument of claim 14 wherein said control means selectively moves said second support prong between a third state and a fourth state, said third longitudinal axis being more closely aligned with said first longitudinal axis in said third state than in said fourth state, and said third longitudinal axis being noncolinear with said first longitudinal axis in said fourth state.

16. The instrument of claim 15 wherein said first and second support prongs are substantially linear.

17. The instrument of claim 15 wherein said first and second support prongs and said suture support are formed integrally.

18. The instrument of claim 15 wherein said suture support is generally tubular forming a bore, said bore housing a portion of said suture.

19. An instrument for ligation through an endoscopic trocar cannula comprising:

(a) an elongated suture support having an intracorporeal end and extracorporeal end;

(b) a suture having an intracorporeal end and an extracorporeal end, said suture extending along and supported by said elongated suture support, said suture having a cinchable loop at the intracorporeal end thereof with a longitudinal bore therethrough;

(c) an implantable support wire extending through said longitudinal bore for controlling and stabilizing said loop; and

(d) a control means located at the extracorporeal end of said elongated suture support for selectively moving said loop between a collapsed state and an open state.

20. The instrument of claim 19 wherein said suture support is generally tubular forming a bore, said bore housing a portion of said suture in a sliding relationship.

21. The instrument of claim 19 wherein said cinchable loop is closed with a slipknot.

* * * * *

04/14/2004, EAST Version: 1.4.1

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,281,238

DATED : January 25, 1994

INVENTOR(S) : Albert K. Chin, et al.

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, after item (76): Inventor, insert the following:

--item (73): Assignee, Origin Medsystems, Inc., 135 Constitution Drive, Menlo Park, California 94025,--

Signed and Sealed this

Thirtieth Day of August, 1994

Attest:

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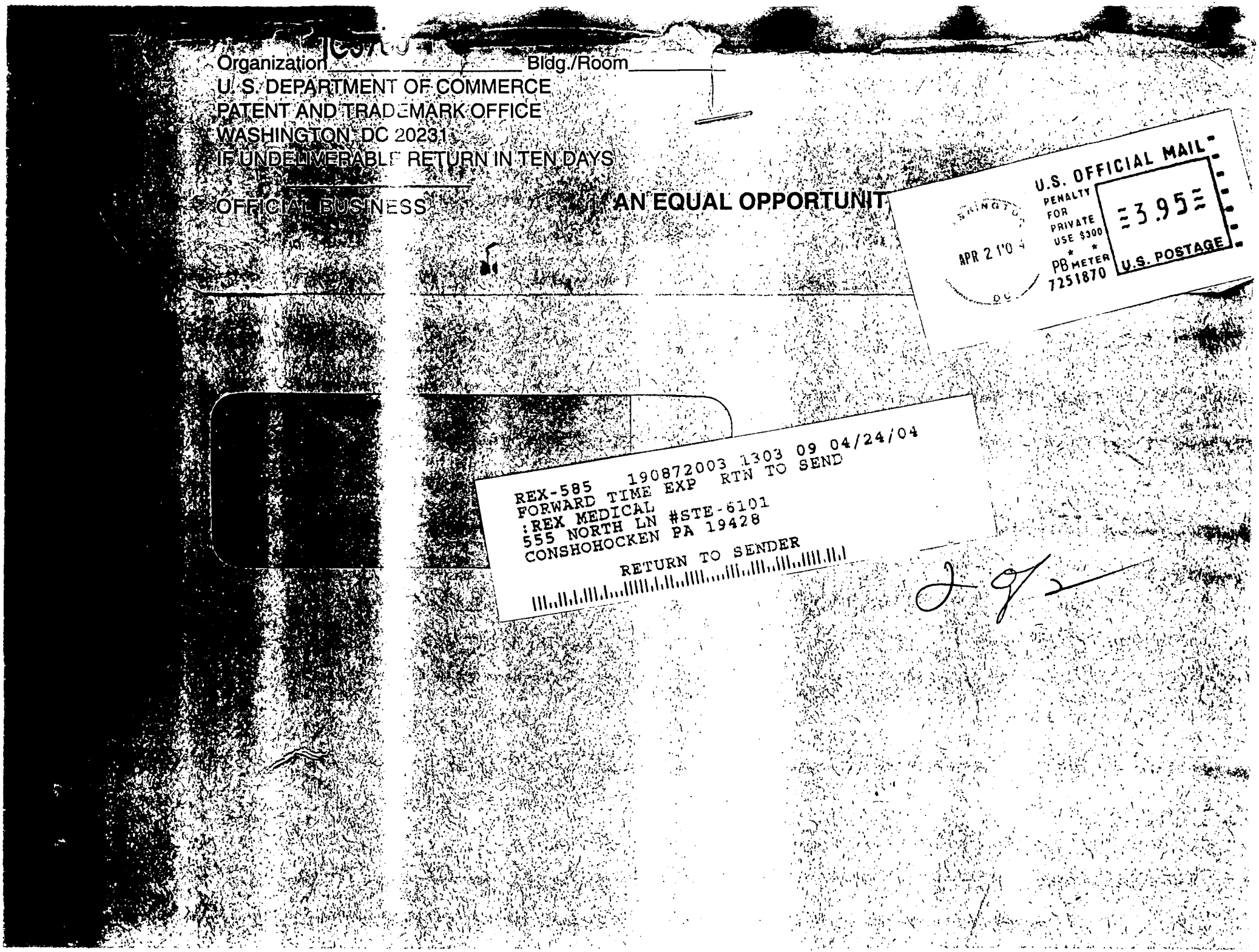
Attesting Officer

Commissioner of Patents and Trademarks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